

## APPARATUS FOR CLEANSING WOUNDS WITH MEANS FOR SUPPLY OF THERMAL ENERGY TO THE THERAPY FLUID

The present invention relates to apparatus and a medical wound dressing for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds, and a method of treating wounds using such apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds.

It relates in particular to such an apparatus, wound dressing and method that can be easily applied to a wide variety of, but in particular chronic, wounds, to cleanse them of materials that are deleterious to wound healing, whilst distributing materials that are beneficial in some therapeutic aspect, in particular to wound healing.

Aspirating and/or irrigating apparatus are known, and tend to be used to remove wound exudate during wound therapy. In known forms of such wound therapy, aspiration and irrigation of the wound take place sequentially.

Each part of the therapy cycle is beneficial in promoting wound healing:

Aspiration applies a negative pressure to the wound, which is beneficial in itself in promoting wound healing by removing materials deleterious to wound healing with the wound exudate, reducing bacterial load, combating peri-wound oedema and encouraging the formation of wound bed granulation tissue.

Irrigation cleanses wounds of materials that are deleterious to wound healing by diluting and moving wound exudate (which is typically relatively little fluid and may be of relatively high viscosity and particulate-filled).

Additionally, relatively little of beneficial materials involved in promoting wound healing (such as cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate) are present in a wound, and are not well distributed in the wound, i.e. they are not necessarily present in parts of the wound bed where they can be potentially of most benefit. These may be distributed by irrigation of the wound and thus aid in promoting wound healing.

The irrigant may additionally contain materials that are potentially or actually beneficial in respect of wound healing, such as nutrients for wound cells to aid proliferation, gases, such as oxygen. These may be distributed by irrigation of the wound and thus aid in promoting wound healing.

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If aspiration and irrigation therapy is applied sequentially to a wound, the two therapies, each of which is beneficial in promoting wound healing, can only be applied intermittently.

10 Thus, the wound will lose the abovementioned known beneficial effects of aspiration therapy on wound healing, at least in part, while that aspiration is suspended during irrigation.

15 Additionally, for a given aspirant flow, whilst materials that are potentially or actually deleterious in respect of wound healing are removed from wound exudate, the removal in a given time period of application of the total irrigate and/or aspirate therapy will normally be less effective and/or slower than with continuous application of aspiration.

20 Even less to be desired, is that while aspiration is not applied to the wound, wound exudate and materials deleterious to wound healing (such as bacteria and debris, and iron II and iron III and for chronic wounds proteases, such as serine proteases) will pool on the wound bed and hinder wound healing, especially in a highly exuding wound. This is especially the  
25 case in chronic wounds.

Depending on the relative volumes of irrigant and wound exudate, the mixed exudate-irrigant fluid and may be of relatively high viscosity and/or particulate-filled. Once it is present and has pooled, it may be more difficult  
30 to shift by the application of aspiration in a conventional sequential aspirate – irrigate – dwell cycle than with continuous simultaneous aspiration of the wound, owing to the viscosity and blockage in the system.

The wound will also lose the abovementioned beneficial effects of irrigation  
35 therapy on wound healing, at least in part, while that irrigation is suspended during aspiration.

These benefits in promoting wound healing include the movement of materials that are beneficial in promoting wound healing, such as those mentioned above.

5 Additionally, for a given irrigant flow, the cleansing of the wound and the distribution by irrigation of the wound of such beneficial materials in a given time period of application of the total irrigate and/or aspirate therapy when such therapy is in a conventional sequential aspirate – irrigate – dwell cycle will normally be less effective and/or slower than with continuous  
10 application of aspiration.

Such known forms of aspiration and/or irrigation therapy systems also often create a wound environment that may result in the loss of optimum performance of the body's own tissue healing processes, and slow healing  
15 and/or in weak new tissue growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

The relevant devices tend not to be portable.  
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It thus would be desirable to provide a system of aspiration and irrigation therapy for a wound, which  
can remove wound exudate and materials deleterious to wound healing from contact with the wound bed,  
25 whilst simultaneously cleansing it and distributing materials that are beneficial in promoting wound healing across it.

It is an object of the present invention to obviate at least some of the abovementioned disadvantages of known aspiration and/or irrigation  
30 therapy systems.

It is a yet further object of the present invention

- a) to obviate at least some of the abovementioned disadvantages of known dialysis systems, and
- 35 b) is portable.

Additionally, it is generally believed that the body's own metabolic activities are at an optimum at or near the temperature naturally occurring in the relevant bodily part.

- 5     Examples of metabolic molecules involved in tissue healing processes that are beneficial in promoting wound healing include enzymes, growth factors and anti-inflammatories, and other physiologically active components of the exudate from a wound.
- 10    These are believed to act best at temperatures found in the relevant bodily part in which they occur, varying between normal temperatures found at the body surface and those at the body core.

15    The body core is at a higher temperature than the surface, but surface temperatures at 33°C and above are still relatively close to core body temperatures of 36 to 38°C. ('normothermic temperature'). Wounds, and in particular chronic wounds, may have a lower temperature, e.g. 24 to 26 °C, i.e. substantially below the optimum temperature. Thus, the temperature of the wound itself is deleterious to wound healing.

20    This may result in slow wound healing, loss of cell proliferation, and/or growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed.

- 25    Conventional wound aspiration and/or irrigation therapy systems thus often create a wound environment under a backing layer where
- a) not only are beneficial materials lost to the site where they can be potentially of most benefit, i.e. the wound bed, when such therapy is applied, but
- 30    b) the wound healing processes, e.g. enzymic activity on tissue growth, are inhibited by sub-optimal temperatures.

Heated dressings are known, but such forms of wound dressing do not simultaneously irrigate the wound environment under the backing layer.

This will result in materials deleterious to wound healing in wound exudate being retained in the wound environment and hindering wound healing in spite of any stimulation of wound healing from wound temperature regulation.

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There would thus be an advantage, in particular in chronic wounds, in providing means for more than one therapy in a single dressing

- a) which not only removes materials deleterious to wound healing from wound exudate, whilst distributing materials that are beneficial in promoting wound healing in contact with the wound bed, but
- b) promotes wound healing by creating a wound environment under the dressing with temperatures which stimulate the activity of metabolic molecules that are beneficial in promoting wound healing, e.g. temperatures near 36 to 38°C. ('normothermic temperature').

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It is an object of the present invention

- a) to obviate at least some of the abovementioned disadvantages of known wound dressing, and
  - b) to provide a system of therapy which cleanses wounds, but also supplies thermal energy to the wound.
- in particular one which
- i) can remove materials deleterious to wound healing from wound exudate, whilst distributing materials that are beneficial in promoting wound healing in contact with the wound bed, and
  - ii) maintains wounds at or near normothermic temperature,

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It is an object of the present invention

- a) to obviate at least some of the abovementioned disadvantages of known wound dressing, and
- b) to provide a system of therapy that conveniently cleanses wounds, but also maintains wounds at or near normothermic temperature.

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A disadvantage of known heated wound dressings is that it is imperative but not easy to avoid the heater, especially an electrical heater, from scorching the wound and/or surrounding surfaces. This is especially so when the dressing is in contact with the wound bed.

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Several devices for applying to the wound to try to do so have been proposed. In one form, a stiff flange or lip extends around the periphery of the dressing to space the surface of the wound in use away from the heater. Such a wound dressing is cumbersome. Whilst it may be acceptable for hospital use, the stiff flange does little for patient comfort, and heightens the risk of inflammation of a wound and/or the leakage of wound exudate. There would be a further advantage in providing such a wound dressing that conforms to the shape of the bodily part to which it is applied.

It is an object of the present invention

a) to obviate at least some of the abovementioned disadvantages of known wound dressing, and

b) to provide a system of therapy which

i) can remove materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed,

ii) which supplies thermal energy to and/or through the wound, and

iii) comprises a conformable wound dressing.

Vascular supply to, and aspiration in, tissue underlying and surrounding the wound is often compromised.

It is a further object of the present invention to provide a system of therapy that also promotes vascular supply to tissue underlying and surrounding a wound, promoting wound healing.

Thus, according to a first aspect of the present invention there is provided an apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds, comprising

a) a fluid flow path, comprising a conformable wound dressing, having a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and

- and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face, the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;
- 5       b) a fluid reservoir connected by a fluid supply tube to an inlet pipe via optional means for supply flow regulation;
- c) optionally means for aspirate flow regulation, connected to a fluid offtake tube: and
- 10      d) at least one device for moving fluid through the wound dressing; characterised in that it comprises
- e) means for providing simultaneous aspiration and irrigation of the wound, such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (optionally via means for supply flow
- 15      regulation) while fluid is aspirated by a device through the fluid offtake tube (optionally or as necessary via means for aspirate flow regulation); and
- f) means for supplying thermal energy to the fluid in the wound,
- 20      Where any pipe is described in connection with the operation of the apparatus as being connected or for connection to a (mating end of a) tube, e.g. a fluid supply tube or fluid offtake tube, the pipe and the tube may form a single integer in the flow path.
- 25      Preferably any such apparatus is an automated, programmable system which can cleanse the wound irrigant and/or wound exudate with minimal supervision.

The present invention in this aspect provides several advantages.

- 30      An advantage of such wound dressings is that it is easy to avoid overheating of the wound and/or surrounding surfaces, especially by electrical heating, since the heating must always pass to the wound through a heat transfer medium (the irrigant). This eliminates direct contact of the
- 35      wound bed with the heater, and irrigant may be used as a heat transfer medium in a highly controllable manner.

The apparatus is most favourable to the wound healing process in chronic wounds, and thus for irrigating, supplying thermal energy to, and cleansing wounds such as diabetic foot ulcers, and especially decubitus pressure ulcers.

- 5 However, thermal energy may also appropriately be applied using the apparatus to aid the healing process in other wound types, such as acute and/or surgical wounds, including burns.

- 10 In a preferred mode, the present invention is used to provide a system of therapy which conveniently cleanses wounds, but also maintains them at or near normothermic temperature.

- 15 Accordingly a preferred type of the apparatus of the invention for irrigating, supplying thermal energy to and cleansing wounds is provided with means for maintaining the wound at or near normothermic temperatures.

- 20 As noted above, the apparatus of the present invention for irrigating, supplying thermal energy to, and cleansing wounds has a direct effect on active components of fluid in contact with the wound, in particular solutes or disperse phase species that are beneficial in promoting wound healing that are in contact with the wound bed. Additionally, cell mitochondria aid proliferation and hence wound healing, in particular in chronic wounds, and are stimulated by near infrared radiation. .

- 25 Application of such radiation to the wound resulting in an increase in cell proliferation in the tissue underlying to the wound, and in the breaking strength of the new tissue.

- 30 Other physiologically active components of the cells in the tissue underlying the wound that are beneficial in promoting wound healing may also be stimulated by radiation on the wound. .

- 35 Another advantage, in particular in chronic wounds, in providing apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing a wound according to the present invention is that it provides means for providing more than one therapy continuously in a single dressing.



Thus, application of an irrigant to a wound under simultaneous aspiration and heating creates a wound environment that is exposed to the continuous beneficial effects of both aspects of the therapy for wound healing.

- 5 This is as opposed to the sequential intermittent application of irrigant flow and aspiration and/or heating in known aspirating and/or irrigating apparatus. The latter result in less than optimum performance of the body's own tissue healing processes, and slower healing and/or weaker tissue growth that does not have a strong three-dimensional structure adhering  
10 well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

Thus, the use of the apparatus of this first aspect of the present invention for aspirating, irrigating, supplying thermal energy to and/or cleansing  
15 wounds retains and enhances the beneficial effects of aspiration in respect of wound healing by continuous and preferably constant aspiration. These include removing materials deleterious to wound healing with the wound exudate, reducing bacterial load, combating peri-wound oedema and encouraging the formation of wound bed granulation tissue.

20 Preferred embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating, supplying thermal energy to and/or cleansing chronic wounds apply a milder negative pressure than in conventional negative pressure therapy (which is too aggressive for the  
25 fragile tissues of many such wounds). This leads to increased patient comfort, and lessens the risk of inflammation of the wound.

The removal of wound exudate in a given time period of application of the total irrigate and/or aspirate therapy will normally be more effective and/or  
30 faster than with a conventional sequential intermittent aspiration and/or irrigation therapy.

Even more desirably, since simultaneous aspiration and irrigation is applied to the wound, wound exudate and materials deleterious to wound healing  
35 (such as bacteria and debris, and iron II and iron III and for chronic wounds proteases) will not pool on the wound bed and hinder wound healing.

This is especially important in highly exuding wounds, e.g. chronic wounds.

The resulting mixed exudate-irrigant fluid will usually be of relatively lower viscosity.

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Because simultaneous aspiration and irrigation of the wound provides continuous removal at a constant relatively high speed, the fluid it does not have to be accelerated cyclically from rest, and will be easier to shift than with known forms of aspiration and/or irrigation therapy systems with a conventional sequential aspirate – irrigate – dwell cycle.

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This will thus exert a greater net effect on the removal of adherent bacteria and debris.

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This is especially the case in those embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds where there is an inlet manifold (as described in further detail hereinafter) that covers and contacts most of the wound bed with openings that deliver the fluid directly to the wound bed over an extended area.

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The present form of aspiration and/or irrigation therapy systems also often create a wound environment for better distribution of materials that are beneficial in some therapeutic aspect, in particular to wound healing, that are present in a wound, but may not be well distributed in the wound, e.g. in a highly exuding wound. (These include cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate.) and/or

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materials in the irrigant that are potentially or actually beneficial in respect of wound healing, such as nutrients for wound cells to aid proliferation, gases, such as oxygen.

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This is especially the case in those embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds where there is an inlet manifold.

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This covers and contacts most of the wound bed with openings that deliver the fluid directly to the wound bed over an extended area.

5 It will be seen that the balance of fluid between fluid aspirated from the wound and irrigant supplied to the wound from the irrigant reservoir may provide a predetermined steady state concentration equilibrium of materials beneficial in promoting wound healing over the wound bed. Simultaneous aspiration of wound fluid and irrigation at a controlled flow rate aids in the attainment and maintenance of this equilibrium

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Examples of means for supplying thermal energy to the fluid in the wound include as may be appropriate conducted thermal energy, electromagnetic radiation of an appropriate wavelength, or (less often) as convected thermal energy.

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In the present apparatus, heat will usually be conducted to the wound bed by the irrigant and/or wound exudate within the dressing.

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However, thermal energy may as appropriate be supplied to the irrigant and/or wound exudate within the dressing, and may be applied to the fluid by any suitable means, at any suitable point, often depending on particular components and/or materials that are used.

Examples of such means include

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a) direct conductive contact of the irrigant and/or wound exudate with a heater and/or conductively heated component of the apparatus flow path;

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b) direct electromagnetic irradiation at an appropriate wavelength, e.g. infrared and/or near infrared from a radiative heater of the irrigant fluid and/or wound exudate; and/or

c) electromagnetic irradiation from a radiative heater of a component of the apparatus flow path that absorbs electromagnetic irradiation at an appropriate wavelength, e.g. infrared and/or near infrared and is in direct conductive contact with the irrigant and/or wound exudate.

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Accordingly, one embodiment of the present apparatus for irrigating, supplying thermal energy to and cleansing wounds supplying thermal energy to and cleansing wounds is characterised in that it comprises means for providing and conducting thermal energy to the fluid in the wound.

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Another embodiment of the present apparatus for irrigating, supplying thermal energy to and cleansing wounds is characterised in that it comprises means for supplying electromagnetic radiation of an appropriate wavelength to the fluid in the wound.

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Another embodiment of the present apparatus for irrigating, supplying thermal energy to and cleansing wounds is characterised in that it comprises means for supplying electromagnetic radiation of an appropriate wavelength to the fluid in the wound.

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The heater of the irrigant fluid and/or wound exudate and/or heated component of the apparatus flow path may be at any convenient or appropriate position or component of the apparatus flow path.

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Examples include a heater and/or conductively heated component of the apparatus flow path upstream of any outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer of the wound dressing,

a) mounted distally of the body on, in or inside of the dressing;

b) mounted in, on, at or near one or more of the fluid inlet pipe(s)

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c) mounted in, on, at or near one or more of the connectors in the tubes that form the flow path of the apparatus; and/or

d) mounted in, on, at or near the reservoir.

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As noted above, the irrigant and/or wound exudate fluid in the interior of the wound dressing is beneficially maintained at a temperature that is at or near the temperature naturally occurring in the relevant bodily part and/or normothermic temperature.

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The desired or optimum temperature of the wound will substantially determine

- a) the position along the apparatus flow path or the component of the apparatus flow path where the heater and/or conductively heated component of the apparatus flow path is mounted relative to the dressing;
- 5 b) the flow rate of irrigant fluid and/or wound exudate;
- c) the temperature to which the point of supply of thermal energy to apparatus is raised;
- d) the thermal insulation of the system in which the fluid moves and heat is conducted to the wound; and/or
- 10 e) the nature of the heater.

In examples of direct conductive contact of the irrigant and/or wound exudate with a heater and/or conductively heated component of the apparatus flow path, the heater may be or be connected to a heat  
15 exchanger mounted in conductive contact with irrigant and/or wound exudate at an appropriate point in the system in which the fluid moves and heat is conducted to the wound.

The heat exchanger may comprise an array of thermally conductive  
20 extended surfaces, such as fins, baffles or other like structures of conductive material in a more convoluted form with a relatively large surface area and which transfer thermal energy when a temperature drop is applied over them, mounted in conductive contact with irrigant and/or wound exudate, with spaces therebetween such that wound irrigant and/or  
25 wound exudate may move through the spaces.

Alternatively, where appropriate it may be provided in the form of a like array of conductive hollow structures, such as pipes, tubes or other like  
30 structures in the apparatus flow path, through which a heat exchanger fluid moves and transfers heat from a heat source to be conducted to the wound).

The array of conductive hollow structures may consist essentially of small apertures or pores that may form such bores, channels, conduits and/or  
35 passages through a heated metal sinter, such as one of e.g. stainless steel.

This is mounted in conductive contact with irrigant and/or wound exudate in the apparatus flow path, through which the fluid moves, so that heat is conducted to the wound.

- 5    Such a heat exchanger may be outside the wound space and the backing layer or within the wound space and under the backing layer.

If it is outside the wound space and the backing layer, it is preferably as close to the wound dressing backing layer as possible.

- 10   Examples of conductive heaters include:

- a) an electric heater mounted in conductive contact with irrigant and/or wound exudate (but electrically insulated from the fluid and the system in which the fluid moves and heat is conducted to the wound).

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The heater may inter alia comprise:

- i) an array of electrically resistive but conductive wires, fibres, filaments, strands or other like structures that generate thermal energy when a voltage drop is applied over them.

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The array may be a parallel array with spaces therebetween, and the wound irrigant and/or wound exudate may move through the spaces.

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Alternatively, where appropriate it may be provided in the form of non-woven or woven fabric, such as a woven layer or sheet. This may as appropriate be used essentially as a flat sheet or membrane of material in a more convoluted form, e.g. conformed to the form of other structures such as pipes, tubes, etc. in the apparatus flow path, as a duct, sheath, or casing, or other like structure.

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Depending on any pressure differential across it may require other materials on or in it to stiffen, reinforce or otherwise strengthen it.

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The material of the heater may have a positive or (less preferably) a negative thermal coefficient of resistance.

A control feedback circuit is needed with a negative coefficient of resistance for temperature regulation.

5 Materials that are described by way of example herein to be suitable for use in this aspect of the present invention will be capable of this function.

10 Depending on other components and/or materials that are present, examples of suitable materials include carbon fibres and fabric, such as a woven layer or sheet, which may as appropriate be made essentially of carbonised acrylate, such as polyacrylonitrile and copolymers thereof.

15 ii) an electrically insulating flat sheet or membrane substrate that has sites on its surface that are connected by an array of electrically resistive but conductive tracks, traces, outlines, or other like structures, e.g. filled channels, conduit and the like, and, e.g. etched foil, which generate thermal energy when a voltage drop is applied over them.

20 The array may be a parallel array with spaces therebetween, connected together at each end, or comprise or consist essentially of one or more such integers

25 in a spiral, or in a meandering, tortuous, winding, zigzag, serpentine or boustrophedonic (i.e. in the manner of a ploughed furrow) pattern.

30 Examples of suitable materials for the array of electrically resistive but conductive tracks, traces, outlines, or other like structures include carbon and/or metals, such as Thermion<sup>™</sup>, a nickel-coated non-woven carbon fabric and resistance heating alloys, such as Kanthal<sup>™</sup>, Alkrothal<sup>™</sup>, Nikrothal<sup>™</sup>, and Nifethal<sup>™</sup>.

35 For the electrically insulating flat sheet or membrane substrate, suitable materials include PTFE, polyamides, and

materials such as aromatic polysulphones, polyethersulphones, polyetherether-sulphones, polyketones, polyetherketones; and polyetherether-ketones, and sulphonated derivatives thereof, and mixtures thereof; and  
5 expoxy resins. .

The array of electrically resistive but conductive tracks, traces, outlines, or other like structures, may be generated by etching or engraving, e.g. with electron beam irradiation and/or with fluid  
10 chemicals.

Alternatively, where appropriate it may be provided by printing, imprinting, stamping or vapour deposition of conventional type.

15 iii) an array of electrically resistive but conductive, mutually connected thermocouples that are potentially capable of generating thermal energy by the Peltier effect when a voltage drop is applied over them.

20 The array may be a parallel array with spaces therebetween, and the wound irrigant and/or wound exudate may move through the spaces.

Alternatively, it may be permanently or releasably attached to the surface of a substrate of the type described by way of example  
25 under ii) as suitable for use in this aspect of the present invention.

Depending on other components and/or materials that are present, examples of suitable materials include thermoelectric modules comprising pellets of bismuth telluride doped with selenium and  
30 antimony of different conductivity, the thermocouple pairs being connected in series and sandwiched between ceramic substrates.

In the Peltier effect when a voltage drop is applied over a thermocouple, one part potentially undergoes heating, and can thus  
35 supply thermal energy to the wound through a heat transfer medium (the irrigant).



The other part undergoes cooling and can thus act as a thermal pump from the ambient to the fluid irrigant and exudate in the apparatus flow path to the wound.

5           However, thermal energy transfer in this highly controllable manner requires orientation of the thermocouple array such that the side capable of gaining thermal energy by the Peltier effect is in conductive contact with the irrigant and/or wound exudate,.

10           Examples of a) i) & ii) include a foam reservoir dressing, such as Allevyn (<sup>TM</sup>, Smith & Nephew) and Tielle (<sup>TM</sup>, Johnson & Johnson), having an electrical heater, mounted distally of the body on it.

15           b) an inductive heater element mounted in conductive contact with irrigant and/or wound exudate (but electrically insulated from the fluid and the system in which the fluid moves and heat is conducted to the wound).

20           The heater may inter alia comprises a piece of ferromagnetic material, such as magnetic stainless steel in conductive contact with irrigant and/or wound exudate, and an inductive source that will be adjacent (but not necessarily attached) to the dressing in use, but may otherwise be remote from the wound).

25           Examples of the latter include a ferromagnetic coil, spiral, helix or spiral helix, or loop or a more convoluted form, e.g. a meandering, tortuous, winding, zigzag, serpentine or boustrophedonic (i.e. in the manner of a ploughed furrow) pattern, in particular in one plane, of an inductive often highly conductive material, connected to an alternating electrical potential source.

30           This is potentially capable of generating thermal energy in the core when a varying potential is applied to the coil, spiral or spiral helix, or loop or a more convoluted form.

35           This is often at mains voltage and frequency at the location where the device is used, though a range of either may be used.

- c) a heater mounted in conductive contact with irrigant and/or wound exudate to which it transfers thermal energy to the fluid in recirculation from a heat source within it, which is a fuel cell.

- 5 In this, atmospheric oxygen and/or other molecules oxidise one or more species of fuel molecules, often in a catalytic bed.

10 Examples of fuel materials that have a strong oxidation exotherm include gases, where the gaseous phase of the aerosol system is air and a fuel gas, such as hydrogen or an alkane, such as methane, ethane and butane.

15 The catalyst is often solid particulates, such as composites of copper and rare earth oxides, such as optionally samaria doped ceria. comprised in a crystalline material for convenient handling; or platinum powder coated onto carbon paper or cloth.

- 20 d) a heater mounted in conductive contact with irrigant and/or wound exudate to which it transfers thermal energy to the fluid in recirculation from a heat source within it, which is a material that undergoes a highly exothermal phase change.

Examples of d) include

- 25 i) a heater containing materials that undergo a highly exothermal crystallisation or solidification phase change, such as supersaturated solutions of chemicals, such as metal ion salts.

30 Sodium thiosulphate is a source of a strong crystallisation exotherm, as is sodium acetate solution.

The fluid or solid material is often comprised in one or more conformable hollow bodies.

35 These may be defined by, for example a polymer film, sheet or membrane, such as a bag, chamber, pouch or other structure, of the backing layer, e.g. of polymer film, for convenient handling.

In the case where the heat source is in the form of a crystallisation system, such as one based on sodium thiosulphate, the bag, chamber, pouch or other structure is often provided with a source of mechanical shock that is appropriate for inducing crystallisation.

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Examples include a catastrophically resiliently flexible or stiff metal button, such as one of e.g. aluminium or stainless steel. .

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Such heaters are less preferred than an electrical heater, since electrical heating can give constant heating intensities in a highly controllable manner. In contrast, a strong crystallisation or solidification exotherm is less controllable or constant.

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- ii) a heater containing materials that undergo an exothermal condensation phase change, i.e. from gaseous or volatile products, such as the Freon hydrocarbon series to liquids. Preferred materials include, in particular those that condense at or near normothermic temperature. Such a heater of the irrigant fluid and/or wound exudate may be operated as a heat pump that absorbs thermal energy, e.g. from the environment of a component of the apparatus flow path into the component of the apparatus flow path.

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In examples of

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- a) direct electromagnetic irradiation at an appropriate wavelength, e.g. infrared and/or near infrared from a radiative heater of the irrigant fluid and/or wound exudate; and/or
- c) electromagnetic irradiation from a radiative heater of a component of the apparatus flow path that absorbs electromagnetic irradiation at an appropriate wavelength, e.g. infrared and/or near infrared and is in direct conductive contact with the irrigant and/or wound exudate.

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The heater usually works at such temperatures as will deliver 34 to 55 ° C, preferably 35 to 42 ° C, and optimally 36 to 38° C at the wound bed.

Examples of sources of direct or indirect electromagnetic irradiation of the irrigant fluid and/or wound exudate at an appropriate wavelength include infrared and/or near infrared from a radiative heater.

- 5 In the apparatus the type and materials of the heater will be largely determined by its specific function and the wavelengths and intensities to be applied to the fluid within the far infrared, mid infrared or near infrared spectrum, and its position in the apparatus of the invention.
- 10 Examples of suitable wavelengths to apply to the fluid include:  
for the far infrared, 4 to 1000 micrometre,  
for the mid infrared, 1.4 to 4 micrometre, and  
for the near infrared, 0.75 to 1.5 micrometre.
- 15 Examples of suitable levels of intensity include those conventionally used in medical applications and known to the skilled person.

- The higher end of these ranges are potentially more suitable for hospital use, where relatively high intensity infrared or near infrared irradiation at  
20 relevant wavelengths may be used safely under professional supervision.

Such a device may also suitably be one that is capable of pulsed, continuous, variable, and/or automated and/or programmable operation.

- 25 Examples include
- i) a radiative heater that is an incandescent filament lamp, light or other like structure, which is a source of radiation at relevant wavelengths to be applied to the fluid, e.g. infrared or near infrared irradiation. Examples of i) include a heater that is a small infrared lamp, mounted  
30 on an infra-red transparent dressing backing layer;
- ii) a radiative heater that is a high-thermal energy, high-intensity LED (light emitting diode) or other like structure, which is a source of radiation at relevant wavelengths to be applied to the fluid, e.g. infrared or near infrared irradiation; and

- iii) a radiative heater that is a high-thermal energy, high-intensity source of radiation at relevant wavelengths to be applied to the fluid, e.g. infrared or near infrared irradiation.

5 The type and materials of the heater will be largely determined by its specific function and the wavelengths and intensities to be applied to the fluid within the spectrum, and its position in the apparatus of the invention.

- 10 d) Any r.f. and/or microwave frequency signal generator may be used provided temperatures at the wound do not exceed 38 to 40°C, and optimally 36 to 38°C.

15 Examples of sources of direct or indirect electromagnetic irradiation of the irrigant fluid and/or wound exudate at an appropriate wavelength also include radio-frequency e.m.r. in a range of 3 to 300 MHz, such as 10 to 100 MHz, such as 20 to 50 MHz.

20 Examples of preferred frequencies include microwave frequencies, using a microwave magnetron, in a range such as 1 to 300 GHz, such as 1 to 100 GHz, e.g. 1 to 50 GHz.

25 It will be appreciated that at these frequencies, in the range of microwave frequencies in particular, thermal energy is not just transferred to the fluid by simply being absorbed by the fluid and conducted to the wound. It is induced in the molecules in the fluid in the wound by radiation at an optimum frequency for such materials.

30 In all the above radiative heaters of the irrigant fluid and/or wound exudate, the electromagnetic irradiation from a radiative heater may pass into the fluid in the flow path directly, usually through a 'window' that is transparent to the relevant wavelengths to be applied to the fluid.

35 Amongst those materials that are suitable are glass; carbon fibres (which may be in a parallel array with spaces therebetween) and carbon fabric, such as a woven layer or sheet.

This may as appropriate be made essentially of carbonised acrylate, such as polyacrylonitrile and copolymers thereof; and various well-known polymers.

5 The transmissive structures may, alternatively or additionally, effectively be in the form of optical fibre(s) or waveguides of conventional type, e.g.

a) a tube, pipe, duct, fibre, filament, strand or other like structure, e.g. of carbon or the materials mentioned above, which is transparent to the relevant wavelengths to be applied to the fluid,

10 b) coated, enclosed or enveloped by a coating, layer, sheet, skin or concentric tube, pipe, duct, sheath, or casing, or other like structure, of material on its outer face that is opaque and reflective to the relevant wavelengths.

15 These may pass at any relevant position along the apparatus flow path into the apparatus flow path where the heat is desired to be applied.

In one embodiment, they will pass under and/or through the backing layer of the dressing.

20

The transmissive structures may effectively be in the form of optical fibre(s) formed by

a) at least one inlet pipe and/or fluid supply tube and/or and/or at least one outlet pipe and/or fluid offtake tube, which passes through and/or under the wound-facing face, and is transparent or translucent to the relevant wavelengths to be applied to the fluid in the wound, and preferably to those that are optimum for wound healing,

25

b) coated, enclosed or enveloped by a coating, layer, sheet, skin or concentric tube, pipe, duct, sheath, or casing, or other like structure, of material on its outer face that is opaque and reflective to the relevant wavelengths.

30

35

An advantage of such wound dressings is that these optical fibres may also serve as diagnostic 'keyholes' into the dressing to the wound bed in order to inspect the wound and assess its status. This is a significant advantage, in particular in chronic wounds.

5

As noted above, radiative energy may be absorbed by a component of the apparatus flow path that absorbs electromagnetic irradiation at an appropriate wavelength, e.g. infrared and/or near infrared and is in direct conductive contact with the irrigant and/or wound exudate.

10

Thus a radiative heater may be radiatively connected to a component of the apparatus flow path that absorbs electromagnetic irradiation at an appropriate wavelength, e.g. infrared and/or near infrared and is in direct conductive contact with the irrigant and/or wound exudate, e.g. by an air gap, the component containing a suitable absorbent and transmissive structure, e.g. an aqueous fluid, such as a hydrogel, that conducts heat through it to the irrigant fluid.

15

20 The temperature of the wound under the wound-facing face of the backing layer of the wound dressing is generally held at a desired level, often that for optimum performance of the wound healing process, such as a temperature found in the relevant bodily part, often within a range of temperatures such as 34 to 55 °C, preferably 35 to 42 °C, and optimally 36 to 38°C at the wound bed. The temperature of the wound under the wound-facing face of the backing layer of the wound dressing is generally held at a constant level throughout the desired length of therapy, but may be varied cyclically in a desired regime.

25

30 However, the temperatures noted above, which are at or near the temperature naturally occurring in the relevant bodily part may not provide a system for optimum performance of the wound healing process. It may be desirable that the interior of the wound dressing is more beneficially maintained at a temperature that degrades such molecules in the fluid in the wound, e.g. an appropriate optimum degradation temperatures for such materials, rather than at normothermic temperature.

35

This may be the case in particular in chronic wounds, with relatively high concentrations of materials that are deleterious to wound healing.

5 Other molecules involved in wound processes that are detrimental to wound healing include or gaseous or volatile by-products, such as carbon dioxide.

10 The irrigant may be warmed to a temperature that tends to degrade and/or outgas such molecules. The degradation or outgassing temperature of each detrimental gas, such as carbon dioxide, in aqueous media is either known or may readily be calculated.

15 Accordingly, another type of this apparatus of the invention for irrigating, supplying thermal energy to and cleansing wounds is provided with means for maintaining the wound at or near a temperature that is deleterious to molecules that are detrimental to wound healing.

20 As noted above, other physiologically active components of the wound cells are beneficial in promoting wound healing and may be stimulated by radiation on the wound under the backing layer.

25 Where these are enzymes, growth factors and anti-inflammatories, cell mitochondria and other physiologically active components of the exudate from a wound, examples of suitable wavelengths and intensities to apply to the fluid in the wound to favour such materials and cell components will be known to the skilled person.

30 The apparatus for irrigating and/or aspirating wounds of the present invention may be used cyclically and/or with reversal of flow.

35 Preferably the present apparatus for aspirating, irrigating and/or cleansing wounds is a conventionally automated, programmable system which can cleanse the wound with minimal supervision.



The means for providing simultaneous aspiration and irrigation of the wound often comprises

a (first) device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, in combination with at

5 least one of

a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing;

means for aspirate flow regulation, connected to a fluid offtake tube, and

means for supply flow regulation, connected to a fluid supply tube;

10

The (first) device will apply negative pressure (i.e. below-atmospheric pressure or vacuum) to the wound bed. It may be applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing.

15 Alternatively or additionally, where appropriate, the aspirate in the fluid offtake tube downstream of the wound dressing may be aspirated into a collection vessel, and the first device may act on fluid such as air from the collection vessel.

20 The (first) device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve.

25

Alternatively, where appropriate the (first) device for moving fluid through the wound may be a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with

30 means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

The (first) device for moving fluid through the wound will often be a pump of any of the following types, or a piped supply of vacuum, applied to fluid

35 downstream of and away from the wound dressing.

In the case of any pump it may be a fixed-speed pump, with (as above) a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve. Alternatively,  
5 where appropriate the pump may be a variable-throughput or variable-speed pump.

The following types of pump may be used as the (first) device:  
reciprocating pumps, such as piston pumps - where pistons pump fluids  
10 through check valves, in particular for positive and/or negative pressure on the wound bed; and  
diaphragm pumps - where pulsations of one or two flexible diaphragms displace fluid with check valves.  
and  
15 rotary pumps, such as:  
progressing cavity  
pumps - with a cooperating screw rotor and stator, in particular for higher-viscosity and particulate-filled exudate; and  
vacuum pumps - with pressure regulators.

20

The (first) device may be a diaphragm pump, e.g. preferably a small portable diaphragm pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

25

Where the pump is a diaphragm pump, and preferably a small portable diaphragm pump, the one or two flexible diaphragms that displace liquid may each be, for example a polymer film, sheet or membrane, that is connected to means for creating the pulsations. This may be provided in  
30 any form that is convenient, inter alia as a piezoelectric transducer, a core of a solenoid or a ferromagnetic integer and coil in which the direction of current flow alternates, a rotary cam and follower, and so on.

Where any second device is applied to the fluid in the fluid supply tube  
35 upstream of and towards the wound dressing, it will usually apply positive pressure (i.e. above-atmospheric pressure) to the wound bed.

As with the (first) device, it may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for supply flow regulation, connected to a fluid supply tube, e.g. a regulator, such as a rotary valve.

5

Alternatively, where appropriate the second device for moving irrigant fluid to the wound may be a variable-throughput device, such as a variable-speed pump, upstream of the wound dressing, thus effectively forming a combination of a second device for moving fluid through the wound with means for supply flow regulation in a single integer.

10

The second device for moving fluid through the wound will often be a pump of any of the following types applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing. It may be a fixed-speed pump, with (as above) a discrete means for supply flow regulation, connected to a fluid supply tube, e.g. a regulator, such as a rotary valve. Alternatively, where appropriate the pump may be a variable-throughput or variable-speed pump.

15

20 The following types of pump may be used as the second device:

reciprocating pumps, such as

shuttle pumps - with an oscillating shuttle mechanism to move fluids at rates from 2 to 50 ml per minute

and

25 rotary pumps, such as:

centrifugal pumps

flexible impeller

pumps - where elastomeric impeller traps fluid between impeller blades and a moulded housing that sweeps fluid through the pump housing.

30

peristaltic pumps - with peripheral rollers on rotor arms acting on a flexible fluid aspiration tube to urge fluid current flow in the tube in the direction of the rotor.

rotary vane pumps - with rotating vaned disk attached to a drive shaft moving fluid without pulsation as it spins. The outlet can be restricted without damaging the pump.

35

The second device may be a peristaltic pump, e.g. preferably a small portable peristaltic pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with irrigant, and for ease of cleaning.

- 5 Where the pump is a peristaltic pump, this may be e.g. an Instech Model P720 miniature peristaltic pump, with a flow rate: of 0.2 – 180ml/hr and a weight of < 0.5 k. This is potentially useful for home and field hospital use.

- 10 Each such pump of any these types may also suitably be one that is capable of pulsed, continuous, variable and/or automated and/or programmable fluid movement. Less usually and less preferably, each such pump of any these types will be reversible.

- 15 As above, the means for supply flow regulation may be a regulator, such as a rotary valve. This is connected between two parts of a fluid supply tube, such that the desired supply flow regulation is achieved.

- 20 If there are two or more inlet pipes, these may be connected to a single fluid supply tube with a single regulator, or to first, second, etc. fluid supply tubes, respectively having a first regulator, a second regulator, etc., e.g. a valve or other control device for admitting fluids into the wound.

- 25 As above, the means for aspirate flow regulation may be similarly provided in a form in which concomitant aspirate flow regulation is possible. It may be a regulator, such as a valve or other control device, e.g. a rotary valve.

- 30 Multiple offtake tubes may be similarly provided with single or multiple regulators, all for aspiration of fluids from the apparatus, e.g. to a aspirate collection vessel, such as a collection bag.

If there is no second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing, it is only possible to apply a negative pressure to the wound.

This is done means of the device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing.

- 5     Operation may e.g. be carried out at a negative pressure of up to 50%atm., typically at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, as is described hereinafter.

10     Examples of suitable and preferred (first) devices include those types of pump that are so described hereinbefore in relation to the first device. This may be a diaphragm pump, e.g. preferably a small portable diaphragm pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

15     Alternatively, if it is desired to apply a net positive pressure to the wound, the means for providing simultaneous aspiration and irrigation of the wound must comprise not only  
a first device for moving fluid through the wound applied to the aspirate in  
20     the fluid offtake tube downstream of and away from the wound dressing, but also  
a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing.

- 25     Operation may then e.g. be carried out at a positive pressure of up to 50%atm., typically at a low positive pressure of up to 20% atm., more usually up to 10% atm. at the wound, as is described hereinafter.

30     Examples of suitable and preferred first devices include those types of pump that are so described hereinbefore in relation to the first device. This may be a diaphragm pump, e.g. preferably a small portable diaphragm pump.

35     This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

Examples of suitable and preferred second devices include those types of pump that are so described hereinbefore in relation to the second device. This may be a peristaltic pump, e.g. a miniature peristaltic pump.

- 5 This is a preferred type of pump, in order to eliminate contact of internal surfaces and moving parts of the pump with irrigant in the fluid supply tube upstream of and towards the wound dressing, and for ease of cleaning.

- 10 It is of course equally possible to apply a negative pressure to the wound, by means of such a combination of  
a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, and  
a second device for moving fluid through the wound applied to the irrigant in  
15 the fluid supply tube upstream of and towards the wound dressing;  
optionally with  
means for supply flow regulation, connected to a fluid supply tube;  
means for aspirate flow regulation, connected to a fluid offtake tube.

- 20 Indeed, as noted below in this regard, preferred embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing chronic wounds that apply a negative pressure include such types of combination of  
a first device, e.g. a diaphragm pump, e.g. preferably a small portable  
25 diaphragm pump, and  
a second device, e.g. a peristaltic pump, preferably a miniature peristaltic pump,  
as described hereinbefore in relation to the device for moving fluid through the wound.

- 30 As noted above, either of the first device and the second device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid  
35 supply tube, in each case, e.g. a regulator, such as a rotary valve, or

a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

5

The higher end of the ranges of % positive and negative pressure noted above are potentially more suitable for hospital use, where they may only be used safely under professional supervision.

- 10 The lower end is potentially more suitable for home use, where relatively high % positive and negative pressures cannot be used safely without professional supervision, or for field hospital use.

- 15 In each case, the pressure on the wound may be held constant throughout the desired length of therapy, or may be varied cyclically in a desired positive or negative pressure regime.

- As noted above, when it is desired to apply a negative pressure to the wound, it is preferred that the means for providing simultaneous aspiration and irrigation of the wound comprise not only  
20 a (first) device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, but also  
a second device for moving fluid through the wound applied to the irrigant in  
25 the fluid supply tube upstream of and towards the wound dressing.

- Accordingly, one embodiment of the apparatus for irrigating, cleansing and/or aspirating wounds of the present invention is characterised in the means for providing simultaneous aspiration and irrigation of the wound  
30 comprises  
a (first) device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, and  
a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing, and  
35 in combination with at least one of  
means for supply flow regulation, connected to a fluid supply tube, and

means for aspirate flow regulation, connected to a fluid offtake tube.

As noted above, either of the first device and the second device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve, or

a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

This combination of

- a) a device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, and
  - b) a device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing,
- may be used to apply an overall positive or negative, or even zero pressure to the wound.

At least one body in the flow path to, over and from the wound bed should have sufficient resilience against the pressure to allow any significant compression or decompression of the fluid occur.

Thus, examples of suitable bodies include those which are or are defined by a film, sheet or membrane, such as inlet or offtake and/or tubes and structures such as bags, chambers and pouches, filled with irrigant fluid, and e.g. the backing layer of the wound dressing, made of elastically resilient thermoplastic materials.

It will be seen that the balance of fluid between aspirated fluid from the wound and irrigant supplied to the wound from the fluid reservoir will thus be largely determined by a means for providing simultaneous aspiration and irrigation of the wound which is a system comprising:



- a) means for aspirate flow regulation and/or a device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, and
- b) means for supply flow regulation and/or a device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing.

As noted above, either of the first device and the second device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve, or a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with means for aspirate flow regulation and/or means for supply flow regulation in a single integer.

The same means may be used to apply an overall positive or negative, or even neutral pressure to the wound.

The appropriate flow rate through the supply tube will depend on a number of factors, such as the viscosity and consistency of each of the irrigant, exudate and mixed exudate-irrigant fluid, and any changes as the wound heals; the level of negative pressure on the wound bed, whether the irrigant in the fluid supply tube upstream of and into the wound dressing is under positive pressure, and the level of such pressure; the level of any pressure drop between the irrigant in the fluid supply tube upstream of the wound dressing and the wound bed, such as across a porous element, e.g. a membrane wound contact layer on the lower surface of an inlet manifold that delivers the fluid directly to the wound bed; means for supply flow regulation; and/or a second device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing; the depth and/or capacity of the wound and

the power consumption needed for a given desired fluid volume flow rate of irrigant and/or wound exudate through the wound.

5 The dressing may comprise an inlet manifold (as described in further detail hereinafter) that covers and contacts most of the wound bed with openings that deliver the fluid directly to the wound bed over an extended area, in the form of one or more inflatable hollow bodies defined by a film sheet or membrane.

10 The (usually small) positive pressure above atmospheric from the irrigation device when both devices are running together should be sufficient to inflate the manifold.

15 The desired fluid volume flow rate of irrigant and/or wound exudate is preferably that for optimum performance of the wound healing process.

20 The flow rate will usually be in the range of 1 to 1500 ml/hr, such as 5 to 1000 ml/hr, e.g. 15 to 300 ml/hr, such as 35 to 200 ml/hr through the supply tube. The flow rate through the wound may be held constant throughout the desired length of therapy, or may be varied cyclically in a desired flow rate regime.

25 In practice, the offtake rate of flow of total irrigant and/or wound exudate will be of the order of 1 to 2000, e.g. 35 to 300 ml/24 hr/cm<sup>2</sup>, where the cm<sup>2</sup> refers to the wound area, depending on whether the wound is in a highly exuding state.

30 In practice, the rate of exudate flow is only of the order of up to 75 microlitres / cm<sup>2</sup> / hr (where cm<sup>2</sup> refers to the wound area), and the fluid can be highly mobile or not, depending on the level of proteases present). Exudate levels drop and consistency changes as the wound heals, e.g. to a level for the same wound that equates to 12.5 – 25 microlitres / cm<sup>2</sup> / hr.

35 It will be seen that the aspirated fluid from the wound will typically contain a preponderance of irrigant from the fluid reservoir over wound exudate.

The necessary adjustments to maintain the desired balance of fluid by means of

- a) the means for aspirate flow regulation and/or downstream device, and
- b) the means for supply flow regulation and/or upstream device for moving  
5 fluid

will be apparent to the skilled person, bearing in mind that as noted above, either of the first device and the second device may be

- a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid  
10 offtake tube, and/or means for supply flow regulation, connected to a fluid supply tube, in each case, e.g. a regulator, such as a rotary valve, or
- a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a (first) device for moving fluid through the wound with means for aspirate flow  
15 regulation and/or means for supply flow regulation in a single integer.

The type and/or capacity of

- a suitable first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound  
20 dressing and/or
- a suitable second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing and/or

will be largely determined by

- 25 a) the appropriate or desired fluid volume flow rate of irrigant and/or wound exudate from the wound, and
  - b) whether it is appropriate or desired to apply a positive or negative pressure to the wound bed, and the level of such pressure to the wound bed
- 30 for optimum performance of the wound healing process, and by factors such as portability, power consumption and isolation from contamination.

As noted above, when it is desired to apply a negative pressure to the wound with the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds to provide simultaneous aspiration and irrigation of the wound, the means for providing simultaneous aspiration and irrigation of the wound may comprise a single device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing or in combination with at least one of means for supply flow regulation, connected to a fluid supply tube, and means for aspirate flow regulation, connected to a fluid offtake tube.

As noted above, the device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, e.g. a regulator, such as a rotary valve, or a variable-throughput device, such as a variable-speed pump, downstream of the wound dressing, thus effectively forming a combination of a device for moving fluid through the wound with means for aspirate flow regulation in a single integer.

The operation of a typical apparatus of this type for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, with one pump will now be described.

Before starting the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, the backing layer of the wound dressing is applied over the wound and conformed to the shape of the bodily part in which the wound is to form a relatively fluid-tight seal or closure.

The means for supply flow regulation, connected to a fluid supply tube, such as a regulator, such as a rotary valve, is usually closed, and the means for aspirate flow regulation (if any), connected to a fluid offtake tube, is opened.

The aspiration pump is started and run to give a negative pressure of up to 50% atm., more usually up to 20% atm., e.g. up to 10% atm. to be applied applies a vacuum to the interior of the dressing and the wound.

- 5 The means for supplying thermal energy to the fluid in the wound in the present apparatus is activated at such time as may be appropriate. This is often once the pump is running, and the means for supply flow regulation is opened.
- 10 (These means for supplying thermal energy to the fluid in the wound in the present apparatus include a heater and/or conductively heated component of the apparatus flow path upstream of any outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer of the wound dressing, which may supply conducted thermal energy, electromagnetic
- 15 radiation of an appropriate wavelength, or (less often) convected thermal energy.)

- The irrigation pump flow rate and any means for fluid supply regulation are then adjusted and/or where the aspiration pump and/or the irrigation pump
- 20 is a variable-speed pump, either or both is/are is adjusted, to maintain the desired balance of fluid at a controlled nominal flow rate and to maintain the desired negative pressure in the interior of the wound dressing.

- The apparatus is then run for the desired length of therapy and with the
- 25 desired pressure regime.

After this period, the irrigation pump is stopped, shortly followed by the aspiration pump.

- 30 The means for supplying thermal energy to the fluid in the wound in the present apparatus is activated at such time as may be appropriate. This is often once the pump is running, and the means for supply flow regulation is opened.

(These means for supplying thermal energy to the fluid in the wound in the present apparatus include a heater and/or conductively heated component of the apparatus flow path upstream of any outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer of the wound dressing, which may supply conducted thermal energy, electromagnetic radiation of an appropriate wavelength, or (less often) convected thermal energy.)

The operation of a typical apparatus for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, with two pumps will now be described.

The necessary changes where the mode of operation is at a net positive pressure of e.g. up to 15% atm., more usually up to 10% atm. at the wound will be apparent to the skilled person.

Such a typical apparatus for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound comprises means for providing simultaneous aspiration and irrigation of the wound which is a combination of

- a) a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, with optional means for aspirate flow regulation, connected to a fluid offtake tube: and
- b) a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing, with optional means for supply flow regulation, connected to a fluid supply tube.

As noted above, either device may be a fixed-throughput device, such as a fixed-speed pump, which will usually require a discrete means for aspirate flow regulation, connected to a fluid offtake tube, e.g. a regulator, such as a rotary valve, or for irrigant flow regulation, connected to a fluid supply tube, either e.g. a regulator, such as a rotary valve, or

a variable-throughput device, such as a variable-speed pump, thus effectively forming a combination of a device for moving fluid through the wound with means for flow regulation in a single integer.

- 5 Before starting the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, the backing layer of the wound dressing is applied over the wound and conformed to the shape of the bodily part in which the wound is to form a relatively fluid-tight seal or closure.

10

Any means for supply flow regulation, connected to a fluid supply tube, such as a regulator, such as a rotary valve, is usually closed, and any means for aspirate flow regulation, connected to a fluid offtake tube, is opened.

15

The aspiration pump is started and run to apply a negative pressure of up to 50% atm., more usually up to 20% atm., e.g. up to 10% atm., to the interior of the dressing and the wound.

- 20 The irrigation pump is then started, so that both pumps are running together, and any means for supply flow regulation is opened.

The irrigation pump flow rate and any means for fluid supply regulation are then adjusted and/or where the aspiration pump and/or the irrigation pump is a variable-speed pump, either or both is/are is adjusted, to maintain the  
25 desired balance of fluid at a controlled nominal flow rate and to maintain the desired negative pressure in the interior of the wound dressing.

- 30 The apparatus is then run for the desired length of therapy and with the desired pressure regime.

After this period, the irrigation pump is stopped, shortly followed by the aspiration pump.

- 35 The means for supplying thermal energy to the fluid in the wound in the present apparatus is activated at such time as may be appropriate.

This is often once the pump is running, and the means for supply flow regulation is opened.

5 (These means for supplying thermal energy to the fluid in the wound in the present apparatus include a heater and/or conductively heated component of the apparatus flow path upstream of any outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer of the wound dressing, which may supply conducted thermal energy, electromagnetic radiation of an appropriate wavelength, or (less often) convected thermal energy.)  
10

In all embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating, supplying thermal energy to and/or  
15 cleansing wounds, a particular advantage is the tendency of the wound dressing to conform to the shape of the bodily part to which it is applied.

The wound dressing comprises a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a  
20 wound and

at least one inlet pipe for connection to a fluid supply tube or tube, which passes through and/or under the wound-facing face, and  
and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,

25 the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure.

The term 'relatively fluid-tight seal or closure' is used herein to indicate one  
30 which is fluid- and microbe-impermeable and permits a positive or negative pressure of up to 50% atm., more usually up to 20% atm. to be applied to the wound. The term 'fluid' is used herein to include gels, e.g. thick exudate, liquids, e.g. water, and gases, such as air, nitrogen, etc.



The shape of the backing layer that is applied may be any that is appropriate to aspirating, irrigating, supplying thermal energy to and/or cleansing the wound across the area of the wound.

- 5 Examples of such include a substantially flat film, sheet or membrane, or a bag, chamber, pouch or other structure of the backing layer, e.g. of polymer film, which can contain the fluid.

10 The backing layer may be a film, sheet or membrane, often with a (generally uniform) thickness of up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

15 Its largest cross-dimension may be up to 500 mm (for example for large torso wounds), up to 100 mm (for example for axillary and inguinal wounds), and up to 200 mm for limb wounds (for example for chronic wounds, such as venous leg ulcers and diabetic foot ulcers).

20 Desirably the dressing is resiliently deformable, since this may result in increased patient comfort, and lessen the risk of inflammation of a wound.

25 Suitable materials for it include synthetic polymeric materials that do not absorb aqueous fluids, such as polyolefins, such as polyethylene e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and polyvinyl alcohol, and mixtures thereof; polysiloxanes; polyesters, such as polycarbonates; polyamides, e.g. 6-6 and 6 - 10, and hydrophobic polyurethanes.

30 They may be hydrophilic, and thus also include hydrophilic polyurethanes.

They also include thermoplastic elastomers and elastomer blends, for example copolymers, such as ethyl vinyl acetate, optionally or as necessary blended with high-impact polystyrene.

35 They further include elastomeric polyurethane, particularly polyurethane formed by solution casting.

Preferred materials for the present wound dressing include thermoplastic elastomers and curable systems.

5 The backing layer is capable of forming a relatively fluid-tight seal or closure over the wound and/or around the inlet and outlet pipe(s).

10 However, in particular around the periphery of the wound dressing, outside the relatively fluid-tight seal, it is preferably of a material that has a high moisture vapour permeability, to prevent maceration of the skin around the wound. It may also be a switchable material that has a higher moisture vapour permeability when in contact with liquids, e.g. water, blood or wound exudate. This may, e.g. be a material that is used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

15 The periphery of the wound-facing face of the backing layer may bear an adhesive film, for example, to attach it to the skin around the wound.

20 This may, e.g. be a pressure-sensitive adhesive, if that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing.

25 Alternatively or additionally, where appropriate a light switchable adhesive could be used to secure the dressing in place to prevent leakage. (A light switchable adhesive is one the adhesion of which is reduced by photocuring. Its use can be beneficial in reducing the trauma of removal of the dressing.)

30 Thus, the backing layer may have a flange or lip extending around the proximal face of the backing layer, of a transparent or translucent material (for which it will be understood that materials that are listed above are amongst those that are suitable).

35 This bears a film of a light switchable adhesive to secure the dressing in place to prevent leakage on its proximal face, and a layer of opaque material on its distal face.

To remove the dressing and not cause excessive trauma in removal of the dressing, the layer of opaque material on the distal face of the flange or lip extending around the proximal wound is removed prior to application of radiation of an appropriate wavelength to the flange or lip.

5

If the periphery of the wound dressing, outside the relatively fluid-tight seal, that bears an adhesive film to attach it to the skin around the wound, is of a material that has a high moisture vapour permeability or is a switchable material, then the adhesive film, if continuous, should also have a high or switchable moisture vapour permeability, e.g. be an adhesive such as used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

10

Where a vacuum, is applied to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing, the wound dressing may be provided with a silicone flange or lip to seal the dressing around the wound. This removes the need for adhesives and associated trauma to the patient's skin.

15

Where the interior of, and the flow of irrigant and/or wound exudate to and through, the dressing is under any significant positive pressure, which will tend to act at peripheral points to lift and remove the dressing off the skin around the wound.

20

In such use of the apparatus, it may thus be necessary to provide means for forming and maintaining such a seal or closure over the wound against such positive pressure on the wound, to act at peripheral points for this purpose.

25

Examples of such means include light switchable adhesives, as above, to secure the dressing in place to prevent leakage.

30

Since the adhesion of a light switchable adhesive is reduced by photocuring, thereby reducing the trauma of removal of the dressing, a film of a more aggressive adhesive may be used, e.g. on a flange, as above.

35

Examples of suitable fluid adhesives for use in more extreme conditions where trauma to the patient's skin is tolerable include ones that consist essentially of cyanoacrylate and like tissue adhesives, applied around the edges of the wound and/or the proximal face of the backing layer of the wound dressing, e.g. on a flange or lip.

Further suitable examples of such means include adhesive (e.g. with pressure-sensitive adhesive) and non-adhesive, and elastic and non-elastic straps, bands, loops, strips, ties, bandages, e.g. compression bandages, sheets, covers, sleeves, jackets, sheathes, wraps, stockings and hose, e.g. elastic tubular hose or elastic tubular stockings that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way; and inflatable cuffs, sleeves, jackets, trousers, sheathes, wraps, stockings and hose that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way.

Such means may each be laid out over the wound dressing to extend beyond the periphery of the backing layer of the wound dressing, and as appropriate will be adhered or otherwise secured to the skin around the wound and/or itself and as appropriate will apply compression (e.g. with elastic bandages, stockings) to a degree that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound,

Such means may each be integral with the other components of the dressing, in particular the backing layer.

Alternatively, it may be permanently attached or releasably attached to the dressing, in particular the backing layer, with an adhesive film, for example, or these components may be a Velcro<sup>™</sup>, push snap or twist-lock fit with each other.

The means and the dressing may be separate structures, permanently unattached to each other.

In a more suitable layout for higher positive pressures on the wound, a stiff flange or lip extends around the periphery of the proximal face of the backing layer of the wound dressing as hereinbefore defined.

- 5 The flange or lip is concave on its proximal face to define a peripheral channel or conduit.

- 10 It has a suction outlet that passes through the flange or lip to communicate with the channel or conduit and may be connected to a device for applying a vacuum, such as a pump or a piped supply of vacuum.

The backing layer may be integral with or attached, for example by heat-sealing, to the flange or lip extending around its proximal face.

- 15 To form the relatively fluid-tight seal or closure over a wound that is needed and to prevent passage of irrigant and/or exudate under the periphery of the wound-facing face of the wound dressing, in use of the apparatus, the dressing is set on the skin around the wound.

- 20 The device then applies a vacuum to the interior of the flange or lip, thus forming and maintaining a seal or closure acting at peripheral points around the wound against the positive pressure on the wound.

- 25 With all the foregoing means of attachment, and means for forming and maintaining a seal or closure over the wound, against positive or negative pressure on the wound at peripheral points around the wound, the wound dressing sealing periphery is preferably of a generally round shape, such as an ellipse, and in particular circular.

- 30 To form the relatively fluid-tight seal or closure over a wound and around the inlet pipe(s) and outlet pipe(s) at the point at which they pass through and/or under the wound-facing face, the backing layer may be integral with these other components.

- 35 The components may alternatively just be a push, snap or twist-lock fit with each other, or adhered or heat-sealed together.

The or each inlet pipe or outlet pipe may be in the form of an aperture, such as a funnel, hole, opening, orifice, luer, slot or port for connection as a female member respectively to a mating end of

- 5 a fluid tube and/or fluid supply tube (optionally or as necessary via means for forming a tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection as a male member respectively to a mating end of a fluid tube and/or fluid supply tube (optionally or as necessary via means for supply flow regulation) or
- 10 a fluid offtake tube.

Where the components are integral they will usually be made of the same material (for which it will be understood that materials that are listed above are amongst those that are suitable).

- 15 Where, alternatively, they are a push, snap or twist-lock fit, they may be of the same material or of different materials. In either case, materials that are listed above are amongst those that are suitable for all the components.

- 20 The or each pipe will generally pass through, rather than under the backing layer. In such case, the backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between the or each pipe and the or each mating tube, or deformation under pressure in any direction.

- 25 It may often be stiffened, reinforced or otherwise strengthened by a boss projecting distally (outwardly from the wound) around each relevant tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection to a mating end of a fluid tube and/or fluid supply tube or fluid
- 30 offtake tube.

Alternatively or additionally, where appropriate the backing layer may have a stiff flange or lip extending around the proximal face of the backing layer to stiffen, reinforce or otherwise strengthen the backing layer.

- 35

The wound dressing may not comprise any integer under the backing layer in the wound in use.

5 However, this may not provide a system to distribute irrigant over a sufficient functional surface area to irrigate the wound at a practical rate to be suitable for use, in particular in chronic wound aspiration and irrigation, with relatively high concentrations of materials that are deleterious to wound healing.

10 It may be advantageous to provide a system where wound irrigant may be distributed more evenly, or pass in a more convoluted path under the dressing over the wound bed.

15 Accordingly, one form of the dressing is provided with a 'tree' form of pipes, tubes or tubules that radiate from an inlet manifold to the wound bed to end in apertures and deliver the aspirating fluid directly to the wound bed via the apertures. Similarly, there is an outlet manifold from which tubules radiate and run to the wound bed to end in openings and collect the fluid directly from the wound bed.

20 The pipes, etc. may radiate regularly or irregularly through the wound in use, respectively from the inlet or outlet manifold, although regularly may be preferred. A more suitable layout for deeper wounds is one in which the pipes, etc. radiate hemispherically and concentrically, to the wound bed.

25 For shallower wounds, examples of suitable forms of such layout of the pipes, etc. include ones in which the pipes, etc. radiate in a flattened hemiellipsoid and concentrically, to the wound bed.

30 Other suitable forms of layout of the pipes, etc. include one which have pipes, tubes or tubules extending from the inlet pipe(s) and/or outlet pipe(s) at the point at which they pass through and/or under the wound-facing face of the backing layer to run over the wound bed. These may have a blind bore with perforations, apertures, holes, openings, orifices, slits or slots  
35 along the pipes, etc.

These pipes, etc. then effectively form an inlet pipe manifold that delivers the aspirating fluid directly to the wound bed or outlet pipe or collects the fluid directly from the wound respectively.

- 5 It does so via the holes, openings, orifices, slits or slots in the tubes, pipes, tubules, etc. over most of the wound bed under the backing layer.

It may be desirable that the tubes, pipes or tubules are resiliently flexible, e.g. elastomeric, and preferably soft, structures with good conformability in  
10 the wound and the interior of the wound dressing.

When the therapy is applied in this way, the layout of the tubes, pipes, tubules, etc. may depend on the depth and/or capacity of the wound.

- 15 Thus, for shallower wounds, examples of suitable forms of such layout of the tubes, pipes, tubules, etc. include ones that consist essentially of one or more of the tubes, etc in a spiral.

A more suitable layout for deeper wounds when the therapy is applied in  
20 this way may be one which comprises one or more of the tubes, etc in a helix or spiral helix.

Other suitable layouts for shallower wounds include one which have blind-bore, perforated inlet pipe or outlet pipe manifolds that aspirate fluid in the  
25 wound when the dressing is in use.

One or both of these may be such a form, the other may be, e.g. one or more straight blind-bore, perforated radial tubes, pipes or nozzles.

- 30 A preferred form of inlet pipe (or less usually) outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively is one that comprise one or more conformable hollow bodies defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure.



It is filled with the irrigant (or less usually) aspirate from the wound, passing through perforations, apertures, holes, openings, orifices, slits or slots in the film, sheet or membrane defining the hollow body or hollow bodies.

- 5 These may be of small cross-dimension, so that they may then effectively form microperforations, microapertures or pores in a permeable integer, for example the polymer film, sheet or membrane.

10 This type of manifold for irrigation (more usually) provides the highest uniformity in the flow distribution of irrigant over the wound at a practical rate to be suitable for use, in particular in chronic wound aspiration and irrigation, and hence to provide a system where materials that are beneficial in promoting wound healing, such as growth factors, cell matrix components, and other physiologically active components of the exudate  
15 from a wound, are distributed more evenly under the dressing over the wound bed.

This type of manifold for irrigation (more usually) is noted below with regard to wound fillers under the backing layer, since it is a resiliently flexible, e.g.  
20 elastomeric, and soft, structure with good conformability to wound shape that is urged by its own resilience against the backing layer to apply gentle pressure on the wound bed, and is therefore also capable of acting as a wound filler. The film, sheet or membrane, often has a (generally uniform) thickness similar to that of films or sheets used in conventional wound  
25 dressing backing layers.

Another suitable layout is one in which  
an inlet pipe and/or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound  
30 respectively  
via inlet and/or outlet tubes, pipes or tubules,  
and the inlet manifold and/or outlet manifold is formed by slots in layers permanently attached to each other in a stack, and  
the inlet and/or outlet tubes, pipes or tubules are formed by apertures  
35 through layers permanently attached to each other in a stack.

As also mentioned herein, the backing layer that is applied may be any that is appropriate to the present system of therapy and permits a positive or negative pressure of up to 50% atm., more usually up to 25% atm. to be applied to the wound.

5

It is thus often a microbe-impermeable film, sheet or membrane, which is substantially flat, depending on any pressure differential on it, and often with a (generally uniform) thickness similar to such films or sheets used in conventional wound dressings, i.e. up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

10

The backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between other components that are not mutually integral, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

15

Such a form of dressing would not be very conformable to the wound bed, and may effectively form a chamber, hollow or cavity defined by a backing layer and the wound bed under the backing layer.

20

It may be desirable that the interior of the wound dressing conform to the wound bed, even for a wound in a highly exuding state. Accordingly, one form of the dressing is provided with a wound filler under the backing layer.

25

This is favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape.

It is urged by its own resilience against the backing layer to apply gentle pressure on the wound bed.

30

The wound filler may be integral with the other components of the dressing, in particular the backing layer. Alternatively, it may be permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange or lip extending from the proximal face, so as not to disrupt the relatively fluid-tight seal or closure over the wound that is needed.

35

Less usually, the wound filler is releasably attached to the backing layer, with an adhesive film, for example, or these components may be a push, snap or twist-lock fit with each other.

5

The wound filler and the backing layer may be separate structures, permanently unattached to each other.

10 The wound filler may be or comprise a solid integer, favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape.

15 Examples of suitable forms of such wound fillers are foams formed of a suitable material, e.g. a resilient thermoplastic. Preferred materials for the present wound dressing include reticulated filtration polyurethane foams with small apertures or pores.

20 Alternatively or additionally, it may be in the form of, or comprise one or more conformable hollow bodies defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, filled with a fluid or solid that urges it to the wound shape.

25 The film, sheet or membrane, often has a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers.

30 That is, up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness, and is often resiliently flexible, e.g. elastomeric, and preferably soft.

30

Such a filler is often integral with the other components of the dressing, in particular the backing layer, or permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange

35 Examples of suitable fluids contained in the hollow body or bodies defined by a film, sheet or membrane include

gases, such as air, nitrogen and argon, more usually air, at a small positive pressure above atmospheric; and liquids, such as water, saline.

- 5 Examples also include gels, such as silicone gels, e.g. CaviCare™ gel, or preferably cellulosic gels, for example hydrophilic cross-linked cellulosic gels, such as Intralene™ cross-linked materials. Examples also include aerosol foams, where the gaseous phase of the aerosol system is air or an inert gas, such as nitrogen or argon, more usually air, at a small positive  
10 pressure above atmospheric; and solid particulates, such as plastics crumbs.

Of course, if the backing layer is a sufficiently conformable and/or e.g. an upwardly dished sheet, the backing layer may lie under the wound filler,  
15 rather than vice versa.

In this type of layout, in order for the wound filler to urge the wound dressing towards the wound bed, it will usually have to be firmly adhered or otherwise releasably attached to the skin around the wound. This is  
20 especially the case in those embodiments where the wound filler and the backing layer are separate structures, permanently unattached to each other.

In such a layout for deeper wounds when the therapy is applied in this way,  
25 the means for such attachment may also form and maintain a seal or closure over the wound.

Where the filler is over the backing layer, and the fluid inlet pipe(s) and outlet pipe(s) pass through the wound-facing face of the backing layer, they  
30 may run through or around the wound filler over the backing layer.

One form of the dressing is provided with a wound filler under the backing layer that is or comprises a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body defined by a film, sheet or membrane, such as  
35 a bag, chamber, pouch or other structure.

It has apertures, holes, openings, orifices, slits or slots, or tubes, pipes, tubules or nozzles. It communicates with at least one inlet or outlet pipe through at least one aperture, hole, opening, orifice, slit or slot.

- 5 The fluid contained in the hollow body may then be the aspirating fluid in the apparatus.

The hollow body or each of the hollow bodies then effectively forms an inlet pipe or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively via the  
10 holes, openings, orifices, slits or slots, or the tubes, pipes or hoses, etc. in the film, sheet or membrane.

When the therapy is applied in this way, the type of the filler may also be  
15 largely determined by the depth and/or capacity of the wound.

Thus, for shallower wounds, examples of suitable wound fillers as a component of a wound dressing include ones that consist essentially of one or more conformable hollow bodies defining an inlet pipe and/or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or  
20 collects the fluid directly from the wound.

A more suitable wound filler for deeper wounds when the therapy is applied in this way may be one which comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, that at  
25 least partly surround(s) a solid integer. This may provide a system with better rigidity for convenient handling.

The wound filler under the backing layer may effectively form an inlet pipe or outlet pipe manifold. If it does not, then in order for aspiration and/or  
30 irrigation of the wound bed to occur, it is appropriate for one or more bores, channels, conduits, passages, pipes, tubes, tubules and/or spaces, etc. to run from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer through or  
35 around the wound filler under the backing layer.

Less usually, the wound filler is an open-cell foam with pores that may form such bores, channels, conduits, passages and/or spaces through the wound filler under the backing layer.

- 5 Where the filler is or comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, it may be provided with means for admitting fluids to the wound bed under the wound dressing.
- 10 These may be in the form of pipes, tubes, tubules or nozzles running from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer through or around the wound filler under the backing layer.
- 15 All of the suitable layouts for shallower wounds that comprise blind-bore, perforated inlet pipe or outlet pipe manifolds that aspirate fluid in the wound when the dressing is in use, that are described hereinbefore, may be used under a wound filler under the backing layer.
- 20 In brief, suitable layouts include ones where one or both manifolds are annular or toroidal (regular, e.g. elliptical or circular or irregular), optionally with blind-bore, perforated radial tubes, pipes or nozzles, branching from the annulus or torus; and/or
- 25 in a meandering, tortuous, winding, zigzag, serpentine or boustrophedonic (i.e. in the manner of a ploughed furrow) pattern, or defined by slots in and apertures through layers attached to each other in a stack.

- 30 The inlet and/or outlet tubes, the fluid tube and the fluid supply tube, etc. may be of conventional type, e.g. of elliptical or circular cross-section, and may suitably have a uniform cylindrical bore, channel, conduit or passage throughout their length, and suitably the largest cross-dimension of the bore may be up to 10 mm for large torso wounds, and up to 2 mm for limb wounds.

The tube walls should suitably thick enough to withstand any positive or negative pressure on them, in particular if the volume of irrigant and/or wound exudate from the wound in is increased by continuing addition to it of wound exudate, and/or fluid passing from a cleansing fluid through a selectively permeable integer, for example the polymer film, sheet or membrane of a two-phase system, such as an aspiration and irrigation unit. However, the prime purpose of such tubes is to convey fluid irrigant and exudate through the length of the apparatus flow path, rather than to act as pressure vessels. The tube walls may suitably be at least 25 micron thick.

10

The bore or any perforations, apertures, holes, openings, orifices, slits or slots along the pipes, etc. or in the hollow body or each of the hollow bodies may be of small cross-dimension.

15 They may then effectively form a macroscopic and/or microscopic filter for particulates including cell debris and micro-organisms, whilst allowing proteins and nutrients to pass through.

20 Such tubes, pipes or hoses, etc. through and/or around the filler, whether the latter is a solid integer and/or one or more resiliently flexible or conformable hollow bodies, are described in further detail hereinbefore in connection with the inlet pipe(s) and outlet pipe(s).

25 The whole length of the apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds should be microbe-impermeable once the wound dressing is over the wound in use.

30 It is desirable that the wound dressing and the interior of the apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds of the present invention is sterile.

35 The fluid may be sterilised in the fluid reservoir and/or the rest of the system in which the fluid moves by ultraviolet, gamma or electron beam irradiation. This way, in particular reduces or eliminates contact of internal surfaces and the fluid with any sterilising agent.

Examples of other methods of sterilisation of the fluid also include e.g. the use of ultrafiltration through microapertures or micropores, e.g. of 0.22 to 0.45 micron maximum cross-dimension, to be selectively impermeable to microbes; and fluid antiseptics, such as solutions of chemicals, such as chlorhexidine and povidone iodine; metal ion sources, such as silver salts, e.g. silver nitrate; and hydrogen peroxide; although the latter involve contact of internal surfaces and the fluid with the sterilising agent.

It may be desirable that the interior of the wound dressing, the rest of the system in which the fluid moves, and/or the wound bed, even for a wound in a highly exuding state, are kept sterile after the fluid is sterilised in the fluid reservoir, or that at least naturally occurring microbial growth is inhibited.

Thus, materials that are potentially or actually beneficial in this respect may be added to the irrigant initially, and as desired the amount is increased by continuing addition.

Examples of such materials include antibacterial agents (some of which are listed above), and antifungal agents.

Amongst those that are suitable are, for example triclosan, iodine, metronidazole, cetrimide, chlorhexidine acetate, sodium undecylenate, chlorhexidine and iodine.

Buffering agents, such as potassium dihydrogen phosphate/ disodium hydrogen phosphate. may be added to adjust the pH, as may local analgesics/anaesthetics, such as lidocaine/lignocaine hydrochloride, xylocaine (adrenoline, lidocaine) and/or anti-inflammatories, to reduce wound pain or inflammation or pain associated with the dressing.



In order to combat the deposition of materials in the flow path from the irrigant, a repellent coating may be used at any point or on any integer in the path in direct contact with the fluid, e.g. on the means for providing simultaneous aspiration and irrigation of the wound or any desired tube or pipe.

Examples of coating materials for surfaces over which the aspirating fluid passes include

anticoagulants, such as heparin, and

high surface tension materials, such as PTFE, and polyamides, which are useful for growth factors, enzymes and other proteins and derivatives.

The apparatus of the invention for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds is provided with means for admitting fluids directly or indirectly to the wound under the wound dressing in the form of a fluid supply tube to a fluid reservoir.

The fluid reservoir may be of any conventional type, e.g. a tube, bag (such as a bag typically used for blood or blood products, e.g. plasma, or for infusion feeds, e.g. of nutrients), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid.

The reservoir may be made of a film, sheet or membrane, often with a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers, i.e. up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness, and is often a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body.

In all embodiments of the apparatus the type and material of the tubes throughout the apparatus of the invention for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds and the fluid reservoir will be largely determined by their function.

To be suitable for use, in particular on chronic timescales, the material should be non-toxic and biocompatible, inert to any active components, as appropriate of the irrigant from the fluid reservoir and/or wound exudate in the apparatus flow path. When in contact with irrigant fluid, it should not  
5 allow any significant amounts of extractables to diffuse freely out of it in use of the apparatus.

It should be sterilisable by ultraviolet, gamma or electron beam irradiation and/or with fluid antiseptics, such as solutions of chemicals, fluid- and  
10 microbe-impermeable once in use, and flexible.

Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as polyethylene, e.g. high-density polyethylene and polypropylene.  
15

Suitable materials for the present purpose also include copolymers thereof, for example with vinyl acetate and mixtures thereof. Suitable materials for the present purpose further include medical grade poly(vinyl chloride).

20 Notwithstanding such polymeric materials, the fluid reservoir will often have a stiff area to resist any substantial play between it and components that are not mutually integral, such as the fluid supply tube towards the wound dressing, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

25

Materials deleterious to wound healing that are removed include oxidants, such as free radicals, e.g. peroxide and superoxide; iron II and iron III;

30 all involved in oxidative stress on the wound bed; proteases, such as serine proteases, e.g. elastase and thrombin; cysteine proteases; matrix metalloproteases, e.g. collagenase; and carboxyl (acid) proteases; endotoxins, such as lipopolysaccharides;  
35 autoinducer signalling molecules, such as homoserine lactone derivatives, e.g. oxo-alkyl derivatives;

inhibitors of angiogenesis such as thrombospondin-1 (TSP-1), plasminogen activator inhibitor, or angiostatin (plasminogen fragment);  
pro-inflammatory cytokines such as tumour necrosis factor alpha (TNF $\alpha$ ) and interleukin 1 beta (IL-1 $\beta$ ),  
5 oxidants, such as free radicals, e.g. , e.g. peroxide and superoxide; and metal ions, e.g. iron II and iron III, all involved in oxidative stress on the wound bed.

10 It is believed that aspirating wound fluid aids in removal from of the materials deleterious to wound healing from wound exudate and/or irrigant, whilst distributing materials that are beneficial in promoting wound healing in contact with the wound.

15 A steady state concentration equilibrium of materials beneficial in promoting wound healing may be set up between in the irrigant and/or wound exudate. Aspirating wound fluid aids in the quicker attainment of this equilibrium

20 Materials beneficial to wound healing that are distributed include cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate and/or  
materials in the irrigant that are potentially or actually beneficial in respect of wound healing, such as nutrients for wound cells to aid proliferation,  
25 gases, such as oxygen.

The conduits through which respectively the irrigant and/or wound exudate passes to and from the wound dressing and  
30 i) preferably have means for modular disconnection and withdrawal of the dressing,  
ii) providing an immediate fluid-tight seal or closure over the ends of the conduits and the cooperating tubes in the rest of the apparatus of the invention so exposed,  
35 to prevent continuing passage of irrigant and/or exudate and cleansed fluid, and cleansing fluid.

The outlet from the means for aspirate flow regulation and/or tubes may be collected and monitored and used to diagnose the status of the wound and/or its exudate.

- 5 Any waste reservoir may be of any conventional type, e.g. a tube, bag (such as a bag typically used as an ostomy bag), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid that has been bled off. In all embodiments of the apparatus, the type and material of the waste reservoir will be largely determined by its function.

10

To be suitable for use, the material need only be fluid-impermeable once in use, and flexible.

- 15 Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as poly (vinylidene chloride).

Suitable materials for the present purpose also include polyethylene, e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and mixtures thereof.

20

In a second aspect of the present invention there is provided a conformable wound dressing, characterised in that it comprises a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound and has

- 25 at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and  
at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,  
the point at which the or each inlet pipe and the or each outlet pipe passes  
30 through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;  
the dressing having means for supplying thermal energy to the fluid in the wound.

- 35 The dressing is advantageously provided for use in a bacteria-proof pouch.

Examples of suitable forms of such wound dressings are as described by way of example hereinbefore.

5 The dressings depicted and described in WO 03/004647 may be used in the apparatus of the present invention with means for supplying thermal energy to the fluid in the wound, e.g. a conductive heater, acting on the irrigant liquid in the flowpath upstream of the wound dressing, e.g. in the fluid supply tube from the irrigant fluid reservoir, usually as close to the wound dressing backing layer as possible.

10

In a third aspect of the present invention there is provided a method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds of the present invention.

15

The present invention will now be described by way of example only with reference to the accompanying drawings in which the means for supplying conducted thermal energy which acts on the irrigant liquid in the flowpath upstream of the wound dressing in the fluid supply tube from the irrigant fluid reservoir as close to the wound dressing backing layer as possible is are omitted from all schematics for clarity.

20

25 Figure 1 is a schematic view of an apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing a wound according to the first aspect of the present invention that has a single device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, in combination with  
30 means for supply flow regulation, connected to a fluid supply tube, and means for aspirate flow regulation, connected to a fluid offtake tube.

30

Figure 2 is a schematic view of another apparatus for aspirating, irrigating, supplying thermal energy to and/or cleansing a wound according to the first  
35 aspect of the present invention that has

35

a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, with means for aspirate flow regulation, connected to a fluid offtake tube; and

- 5 a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing.

10 Figures 3 to 5 are cross-sectional side views of conformable wound dressings, of the second aspect of the present invention for aspirating and/or irrigating wounds.

Figures 6A to D are variants of a two-pump system with essentially identical, and identically numbered, components as in Figure 2, except that there is

- 15 a pump bypass loop (except in Figure 11C).

a filter downstream of the aspirate collection vessel, and  
a bleed regulator, such as a rotary valve, connected to the fluid offtake tube or to the wound space, for the regulation of the positive or negative  
20 pressure applied to the wound.

Figures 7A to C are variants of a two-pump system with essentially identical, and identically numbered, components as in Figures 11, except that they have various means for varying the regulation of the positive or  
25 negative pressure applied to the wound.

Figures 8A and B are variants of a two-pump system with essentially identical, and identically numbered, components as in Figures 11. However, they have alternative means for handling the aspirate flow to the  
30 aspirate collection vessel under negative or positive pressure to the wound in simultaneous aspiration and irrigation of the wound, including in Figure 27B a third device for moving fluid into a waste bag.

Figure 9 is a single-pump system essentially with the omission from the  
35 apparatus of Figures 11 of the second device for moving irrigant fluid into the wound dressing.

Referring to Figure 1, the apparatus (1) for aspirating, irrigating, supplying thermal energy to and/or cleansing wounds comprises

a conformable wound dressing (2), having

a backing layer (3) which is capable of forming a relatively fluid-tight seal or

5 closure (4) over a wound (5) and

one inlet pipe (6) for connection to a fluid supply tube (7), which passes through the wound-facing face of the backing layer (5) at (8), and

one outlet pipe (9) for connection to a fluid offtake tube (10), which passes through the wound-facing face at (11),

10 the points (8), (11) at which the inlet pipe and the outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;

the inlet pipe being connected via means for supply flow regulation, here a valve (14), by the fluid supply tube (7) to a fluid reservoir (12), and

15 the outlet pipe (9) being connected via means for aspirate flow regulation, here a valve (16) and a fluid offtake tube (10) to waste, e.g. to a collection bag (not shown);

a device for moving fluid through the wound (5), here a diaphragm pump (18), e.g. preferably a small portable diaphragm pump, acting on the fluid

20 aspiration tube (13) to apply a low negative pressure on the wound; and

the valve (14) in the fluid supply tube (7), the valve (16) in the fluid offtake tube (10), and the diaphragm pump (18), providing means for providing simultaneous aspiration and irrigation of the wound (5), such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply

25 tube (via the means for supply flow regulation) and moved by the device through the flow path.

The operation of the apparatus is as described hereinbefore.

30 Referring to Figure 2, the apparatus (21) is a variant two-pump system with essentially identical, and identically numbered, components as in Figure 1, except that

there is no means for supply flow regulation in the fluid supply tube (7) from the fluid reservoir (12), and

35 there is

a first device for moving fluid through the wound (5), here a diaphragm pump (18A), e.g. preferably a small portable diaphragm pump, acting on the fluid aspiration tube (13) downstream of and away from the wound dressing to apply a low negative pressure on the wound; with

5 means for negative pressure regulation, here a valve (16) connected to the vacuum tube (13) and a vacuum vessel (aspirant collection jar) (19); and

a second device for moving fluid through the wound (5), here a peristaltic pump (18B), e.g. preferably a small portable diaphragm pump, applied to the irrigant in the fluid supply tube (7) upstream of and towards the wound dressing,

10 the first device (18A) and second device (18B), and the valve (16) in the vacuum tube (10), and the diaphragm pump (18A), providing means for providing simultaneous aspiration and irrigation of the wound (5), such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (via the means for supply flow regulation) and moved by the  
15 devices through the flow path.

The operation of the apparatus is as described hereinbefore

20 Referring to Figures 3 to 5, each dressing (41) is in the form of a conformable body defined by a microbe-impermeable film backing layer (42) with a uniform thickness of 25 micron, with a wound-facing face (43) which is capable of forming a relatively fluid-tight seal or closure over a wound.

25

The backing layer (72) extends in use on a wound over the skin around the wound. On the proximal face of the backing layer (43) on the overlap (44), it bears an adhesive film (45), to attach it to the skin sufficiently to hold the wound dressing in place in a fluid-tight seal around the periphery of the  
30 wound-facing face (43) of the wound dressing.

30

There is one inlet pipe (76) for connection to a fluid supply tube (not shown), which passes through and/or under the wound-facing face (43), and one outlet pipe (77) for connection to a fluid offtake tube (not shown),  
35 which passes through and/or under the wound-facing face (43),



Referring to Figure 3, one form of the dressing comprises a circular sheet (70) that lies under a circular backing layer (72) and is permanently attached to a boss (81), which is e.g. heat-sealed to the backing layer (72).

- 5     An annular layer of foam (74) formed of a suitable material, e.g. a resilient thermoplastic, preferably a reticulated filtration polyurethane foam with small apertures or pores, spaces the sheet (70) from the backing layer and surrounds the boss (81).
- 10    A downwardly dished membrane (75) with openings (76) is permanently attached to the sheet (70) by heat-sealing to form a chamber (77) with the sheet (70).

- 15    An inlet pipe (76) and outlet pipe (77) are mounted centrally in the boss (81) and pass through the backing layer (72).

- 20    The inlet pipe (76) is made of a polyurethane tubular core (not shown) surrounded by an annulus of resistive conductive material, such as one of the resistive alloys noted hereinbefore, which generates thermal energy when a voltage drop is applied over it. It is connected to a cell (78), shown schematically, which applies a voltage drop over it.

- 25    The inlet pipe (76) communicates with the interior of the chamber (77), which thus forms an inlet manifold that distributes heated fluid directly to the wound when the dressing is in use.

- 30    The outlet pipe (77) extends radially immediately under the backing layer (3) and communicates with the inner face of the layer of foam (74), which forms an outlet manifold.

- 30    This form of the dressing is a more suitable layout for shallow wounds

- 35    Another form of dressing is shown in Figure 4. An inlet pipe (76) and outlet pipe (77) are mounted centrally in a boss (81) in, and pass through a backing layer (3). An oblately hemispheroidal filler (88) with an annular groove (89) may be permanently attached to the pipes (76) and (77).

It is formed of a suitable material, e.g. a resilient thermoplastic foam, preferably a reticulated filtration polyurethane foams with small apertures or pores.

- 5 An annular electrical heat pad (90) is mounted around the boss (81) on top of the backing layer (3), which is capable of conducting heat to the wound (5) through the irrigant.

- 10 It may be in the form of non-woven or woven fabric, such as a woven layer or sheet of carbon fibres or a fabric, such as a woven layer or sheet made essentially of carbonised acrylate, such as polyacrylonitrile and copolymers thereof, which generate thermal energy when a voltage drop is applied over it.

- 15 Alternatively, it may be an electrically insulating flat sheet or membrane substrate that has an electrically resistive but conductive printed circuit on it. It is connected to a cell (78), shown schematically, which applies a voltage drop over it.

- 20 The inlet pipe (76) communicates with the wound space at the lowest point of the filler (88). The outlet pipe (77) communicates with the groove (89), and effectively collects the fluid from the wound periphery when the dressing is in use.

- 25 This form of the dressing is a more suitable layout for deeper wounds.

- 30 In Figure 5, an inlet pipe (76) and outlet pipe (77) are mounted centrally in a boss (81) in, and pass through a backing layer (72). An oblatelately spheroidal conformable hollow body (78) is defined by a membrane (79) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape, and is permanently attached to the pipes (76) and (77).

It is formed of a suitable material, e.g. a resilient thermoplastic, preferably a reticulated filtration polyurethane foam with small apertures or pores.

The inflation inlet pipe (350) communicates with the interior of the hollow body (78), to permit inflation of the body (78). The inlet pipe (76) extends through the hollow body (78). The outlet pipe (77) communicates with an outlet manifold formed by a series of radial apertures in a foam disc (87) immediately under the backing layer, that collects the fluid from the wound periphery when the dressing is in use.

An electrical heater (90) is mounted under the boss (81) on top of the backing layer (3), which is transparent to radiant heat, and so permit its transmission to the wound (5) through the irrigant.

It may be in the form of a near infrared radiant heater which generates thermal energy when a voltage drop is applied over it. It is connected to a cell (78), shown schematically, which applies a voltage drop over it.

Referring to Figure 6A, the apparatus (21) is a variant two-pump system with essentially identical, and identically numbered, components as in Figure 2.

Thus, there is  
a means for supply flow regulation, here a valve (14) in the fluid supply tube (7) from the fluid reservoir (12), and  
a first device for moving fluid through the wound (5), here a fixed-speed diaphragm pump (18A), e.g. preferably a small portable diaphragm pump, acting not on the fluid aspiration tube (13), but on an air aspiration tube (113) downstream of and away from an aspirate collection vessel (19) to apply a low negative pressure on the wound through the aspirate collection vessel (19); with  
a second device for moving fluid through the wound (5), here a fixed-speed peristaltic pump (18B), e.g. preferably a small portable peristaltic pump, applied to the irrigant in the fluid supply tube (7) upstream of and towards the wound dressing,

the first device (18A) and second device (18B), and the valve (14) in the fluid supply tube (7), providing means for providing simultaneous aspiration and irrigation of the wound (5), such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (via the means for supply flow regulation) and moved by the devices through the flow path.

There is no means for aspirate flow regulation, e.g. a valve connected to the fluid offtake tube (10).

Since first device (18A) and second device (18B) are fixed-speed, the valve (14) in the fluid supply tube (7) provides the sole means for varying the irrigant flow rate and the low negative pressure on the wound.

The following extra features are present:

The second device, the fixed-speed peristaltic pump (18B), is provided with means for avoiding over-pressure, in the form of a bypass loop with a non-return valve (115). The loop runs from the fluid supply tube (7) downstream of the pump (18B) to a point in the fluid supply tube (7) upstream of the pump (18B).

A pressure monitor (116) connected to the fluid offtake tube (10) has a feedback connection to a bleed regulator, here a motorised rotary valve (117) on a bleed tube (118) running to and centrally penetrating the top of the aspirate collection vessel (19). This provides means for holding the low negative pressure on the wound at a steady level.

A filter (119) downstream of the aspirate collection vessel (19) prevents passage of gas- (often air-) borne particulates, including liquids and micro-organisms, from the irrigant and/or exudate that passes into the aspirate collection vessel (19) into the first device (18A), whilst allowing the carrier gas to pass through the air aspiration tube (113) downstream of it to the first device (18A). The operation of the apparatus is as described hereinbefore

Referring to Figure 6B, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 6A downstream of point A in Figure 6A. The bleed tube (118) runs to the air aspiration tube (113) downstream of the filter (119), rather than into the aspirate collection vessel (19). This provides means for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

Referring to Figure 6C, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 6A upstream of point B in Figure 6A. The second device (18B) is a variable-speed pump, and the valve (14) in the fluid supply tube (7) is omitted. The second device (18B) is the sole means for varying the irrigant flow rate and the low negative pressure on the wound. The operation of the apparatus is as described hereinbefore

Referring to Figure 6D, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 6A downstream of point B in Figure 6A.

The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to the bleed regulator, motorised rotary valve (117) on a bleed tube (118) running to the monitor offtake tube (120). This provides means for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

Referring to Figure 7A, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 6A downstream of point B in Figure 6A.

The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a means for aspirate flow regulation, here a motorised valve (16) in the air aspiration tube (113) downstream of the filter (119).

This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

5

Referring to Figure 7B, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 7A downstream of point B in Figure 6A. The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a means for aspirate flow regulation, here a motorised valve (16), in the fluid offtake tube (10) upstream of the aspirate collection vessel (19).

This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore

Referring to Figure 7C, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 7A downstream of point B in Figure 6A. The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a variable-speed first device (18A), here a variable-speed pump, downstream of the filter (119), and the valve (16) in the fluid offtake tube (10) is omitted.

25

This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore.

30

Referring to Figure 8A, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 7C downstream of point B in Figure 7A, and alternative means for handling the aspirate flow to the aspirate collection vessel under negative or positive pressure to the wound.

35

The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a variable-speed first device (18A), here a variable-speed pump, upstream of the aspirate collection vessel (19), and the filter (119) and the air aspiration tube (113) are omitted. This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore.

Referring to Figure 8B, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 7C downstream of point B in Figure 6A, and alternative means for handling the aspirate flow to the aspirate collection vessel under negative or positive pressure to the wound. The pressure monitor (116) is omitted, as is the feedback connection to a variable-speed first device (18A), here a variable-speed pump, downstream of the aspirate collection vessel (19) and the filter (119). A third device (18C), here a fixed-speed pump, provides means for moving fluid from the aspirate collection vessel (19) into a waste bag (19A). The operation of the apparatus is as described hereinbefore.

Referring to Figure 9, this shows an alternative layout of the essentially identical, and identically numbered, components in Figure 6A upstream of point A in Figure 6A.

It is a single-pump system essentially with the omission from the apparatus of Figure 6A of the second device for moving irrigant fluid into the wound dressing. The operation of the apparatus is as described hereinbefore.

The use of the apparatus of the present invention will now be described by way of example only in the following Example:

Example 1 - Removal of wound proteins and heating a wound with a two-pump apparatus.

5 In this example, a gelatine sheet laid in a cavity wound model represents wound proteins and derivatives to be removed by the two-pump apparatus.

10 The dressing is essentially identical with that in Figure 3, i.e. a form of the dressing with an inlet pipe surrounded by an annulus of resistive conductive material, which is connected to a cell via a circuit with a current control and a switch, and generates thermal energy when a voltage drop is applied over it by the cell.

15 The inlet pipe communicates with the interior of an inlet manifold that distributes heated fluid directly to the wound when the dressing is in use.

A two-pump system is set up essentially as in Figure 2, with an irrigant dispensing bottle – 1000ml Schott Duran, connected to a peristaltic pump (Masterflex) for irrigant delivery, and associated power supply and supply tube,  
20 a diaphragm vacuum pump (Schwarz) for aspiration, and associated power supply and offtake tube, connected to a vacuum vessel (aspirant collection jar) – Nalgene 150ml polystyrene each pump being connected to a dressing consisting of the following elements:

- 25 1. wound-contacting element, comprising a lobed bag with low porosity 'leaky' membrane wound contact layer on the lower surface, impermeable film on the top, and a foam spacer between the two layers to allow free flow of irrigant solution.
- 30 2. a space filling element, comprising a reticulated, open-cell foam (black reticulated foam, Foam Techniques) 30mm thick, 60mm diameter
3. an occlusive adhesive coated polyurethane backing layer top film (Smith & Nephew Medical) with acrylic pressure sensitive adhesive
4. two tubes passing under the occlusive top film, and sealed to prevent leakage of gas or liquid:



- a. one tube centrally penetrating the top film of the wound-contacting element to deliver irrigant into the chamber formed by this film and the porous element;
- b. the other tube of approximately equal length to remove aspirant with the opening positioned just above the top film of the wound contacting element.

Pressure sensor in wound model cavity

Temperature sensor in wound model cavity

10

Preparation of gelatine sheet:

A 20% aqueous solution of gelatine is prepared by weighing gelatine into a glass jar and making it up to the required weight with deionised water. The jar is placed in an oven (Heraeus), at set temperature 85°C.

15

After 60 minutes the jar is removed from the oven and shaken, to encourage mixing. Petri dishes are partially filled with 10g quantities of the gelatine solution and placed in a fridge (LEC, set temperature: 4°C) to set for at least 1 hour. Final thickness of the gelatine slab is ~5mm. Petri dishes containing the gelatine slabs are removed from the fridge at least 2 hours before use.

20

Preparation of test equipment and materials

Irrigant solution (deionised water) and the Perspex wound model are pre-conditioned in an oven (Gallenkamp) at set temperature 37°C, for at least 4 hours before use.

25

For each test, a freshly prepared gelatine slab is removed from a Petri dish and weighed. The Perspex wound model is then removed from the oven and the gelatine slab placed at the bottom of the cavity. Application of the dressing to the wound model is as follows:

30

- the wound contacting element is carefully placed over the gelatine slab
- the foam filler is placed on top of this with the irrigant and aspirant tubes running centrally to the top of the cavity (the foam filler is slit to the centre to facilitate this).

- the side entry port, pre-threaded onto the tubes, is adhesively bonded to the upper surface of the wound model block using an acrylic pressure sensitive adhesive
- the top adhesive coated film is applied over all of the elements and pressed down to give a seal on all sides, and especially around the tube entry/exit point

Application of the dressing to the wound model is the same for all tests performed. All tubing used is the same for each experiment (e.g. material, diameter, length).

#### Simultaneous Irrigation & Aspiration

A schematic diagram of the system used in the experiment is shown below. For the experiment most of the apparatus (not including the pumps, power supply, and connecting tubing to and from the pumps) is placed in an oven (Gallenkamp, set temperature: 37°C), on the same shelf.

Before starting the irrigation pump a vacuum is drawn on the system to check that the dressing and tube connections are substantially airtight.

The pumping system is controlled to give a pressure at the vacuum vessel of approximately -75mmHg before opening the system up to include the dressing).

Once system integrity has been confirmed, the irrigation pump is started (nominal flow rate: 50ml/hr), i.e. both pumps running together.

The means for supplying thermal energy to the fluid in the wound in the present apparatus is then activated, i.e. the switch is closed, so that a voltage drop is applied over the annulus of resistive conductive material, and it generates thermal energy, which is conducted to the irrigant liquid passing through the inlet pipe into the manifold chamber. The current control is adjusted to maintain a temperature at the wound bed under the wound-facing face of the backing layer of the wound dressing at a constant level throughout the experiment of 36 to 38°C.

Timing of the experiment is started when the advancing water front within the irrigant tube is observed to have reached the top of the dressing.

- 5 After 60 minutes, the means for supplying thermal energy to the fluid in the wound in the present apparatus is deactivated, i.e. the switch is opened, so that a voltage drop is no longer applied over the annulus of resistive conductive material.

- 10 The irrigation pump is stopped, shortly followed by the vacuum (aspiration) pump. Aspirant liquid collected in the vacuum jar is decanted into a glass jar. The vacuum jar is rinsed with ~100ml of deionised water and this added to the same glass jar. The aspirant solution is placed in an oven (Heraeus, set temperature: 130°C) and dried to constant weight.

#### Sequential Irrigation & Aspiration

- 15 The experimental set up is as for the simultaneous irrigation/aspiration experiment. Before starting the experiment a vacuum is pulled on the system to check that the dressing and tube connections are substantially airtight.
- 20 The pumping system is controlled to give a pressure at the vacuum vessel of approximately -75mmHg before opening the system up to include the dressing.

- 25 Once system integrity has been confirmed, the irrigation pump is started (nominal rate: 186ml/hr) and the means for supplying thermal energy to the fluid in the wound in the present apparatus is then activated, i.e. the switch is closed, so that a voltage drop is applied over the annulus of resistive conductive material. The current control is adjusted to maintain a temperature at the wound bed under the wound-facing face of the backing layer of the wound dressing at a constant level throughout the experiment
- 30 of 36 to 38°C.

The pump is run until the advancing water front in the irrigant tube is observed to have reached the top of the dressing.

The pump is temporarily stopped at this point whilst the vacuum line is sealed (using a tube clamp) and the vacuum pump stopped.

Timing of the experiment is from the point the irrigation pump is restarted.

- 5 The pump is run until 50ml of irrigant has entered the wound model (just over 16 minutes at the rate of 186ml/hr). At this point the means for supplying thermal energy to the fluid in the wound in the present apparatus is deactivated, i.e. the switch is opened, so that a voltage drop is no longer applied over the annulus of resistive conductive material. The irrigant pump  
10 is stopped.

It is observed that during the filling phase of sequential filling and flushing, air trapped in the model wound cavity caused the top film of the dressing to inflate substantially, to a point approaching failure.

15

After a further ~44 minutes (60 minutes from the start of the experiment) the vacuum pump is started and the tube clamp on the aspirant line removed. The wound model is aspirated for 5 minutes.

- 20 Towards the end of this period a small leak is introduced into the top film of the dressing to maximise the amount of fluid drawn from the wound model (it is observed that as the pressure differential between the wound model cavity and the vacuum jar reduced to zero, the flow of aspirant also tended to slow. Introducing a small leak re-established the pressure differential  
25 and the flow of aspirant out of the cavity).

### Conclusions

Using the present apparatus with its means for supplying thermal energy to the fluid in the wound, one is able to achieve and maintain a temperature at  
30 the wound bed under the wound-facing face of the backing layer of the wound dressing at a constant level of 36 to 38°C, while simultaneously irrigating and aspirating the wound model with programmable fluid movement.

35

Simultaneously irrigating and aspirating also removes more of the surrogate wound protein sheet placed at the base of the wound model cavity than sequentially filling and emptying the cavity, even though the amount of liquid entering the wound and the duration of the experiment are the same in both cases. Simultaneously irrigating and aspirating also removes more fluid from the model wound.

Example 2. The combination of simultaneous warmed fluid flow (irrigation) and aspiration (under reduced pressure) on wound bed fibroblasts compared with the exposure of wound bed fibroblasts to repeated fill-empty cycles of warmed fluid flow and aspiration.

An apparatus of the present invention was constructed essentially as in Figure 10, which is an apparatus where an irrigant or fluid of some nature is delivered continually to the wound bed and the resultant wound exudate/fluid mixture is at the same time continually aspirated from the wound. Alternative systems are known where the wound is subjected to repeated iteration of a cycle of fluid delivery followed by a period of aspiration under reduced pressure.

The apparatus comprised a surrogate wound chamber (Minucells perfusion chamber) in which normal diploid human fibroblasts were cultured on 13 mm diameter (Thermanox polymer) cover slips retained in a two part support (Minucells Minusheets). Tissues present in the healing wound that must survive and proliferate were represented by the cells within the chamber. Nutrient medium (DMEM with 10% FCS with 1% Buffer All) to simulate an irrigant fluid/wound exudate mixture, was pumped from a reservoir into the lower aspect of the chamber where it bathed the fibroblasts and was removed from the upper aspect of the chamber and returned to a second reservoir. The wound chamber was maintained at less than atmospheric pressure by means of a vacuum pump in line with the circuit.

The pumps for the circuit were peristaltic pumps acting on silicone (or equivalent) elastic tubing.

The circuit was exposed to a vacuum of no more than 10% atmospheric pressure, 950 mbar and atmospheric pressure varied up to a maximum value of 1044 mbar. The internal diameter of the tubing was 1.0 mm. A total volume for the circuit including the chamber and the reservoir of  
5 between 50 and 220 ml was used. The flow rates used were at a number of values between  $0.1 \text{ ml min}^{-1}$  and  $2.0 \text{ ml}^{-1} \text{ min}^{-1}$ .

First circuit also comprised:

- 10 a) upstream of the wound chamber, a heat exchanger such that the temperature of the nutrient media bathing the cells reaches between 35 °C and 37 °C.

Experiments were conducted that simulated conditions not uncommon for healing wounds whereby the chamber simulating the wound was placed in  
15 a room temperature environment (simulating the low temperatures often experienced in wounds where blood flow is poor), additional chambers heated such that the cells reaches between 35 °C and 37 °C.

An experiment was conducted that simulated conditions that are not  
20 uncommon for healing wounds whereby a fluid was delivered to the wound bed and the application of a vacuum is used to remove the mixture of fluid and exudate to a waste reservoir. An air bleed fluid control valve was additionally positioned in the circuit so that on opening the air bleed occurred for a time and closed the fluid flow, the simulated irrigant  
25 fluid/wound exudate mixture was evacuated from the chamber and the fibroblasts were maintained under a negative pressure relative to the atmosphere. This represents an empty / fill system. 6 cycles of empty/ fill were performed with each fill or empty phase lasting 1 hour.

30 Apparatus was also constructed essentially as in Figure 10, but where either

- a) it was was operated as an empty/fill system with 6 x cycles of 1 hour empty/ 1 hour fill over a total of 25 hours, or  
a) the heat exchanger is omitted, so that the nutrient flow bathing the cells  
35 does not reach between 35 °C and 37 °C and remains at between 18 °C and 20 °C.

### Results and Conclusions

5 The following results were obtained for a circuit comprising a wound chamber as above containing a total volume of nutrient media (154 ml) pumped at a flow rate of  $0.2 \text{ ml min}^{-1}$  and where vacuum was set at 950 mbar and where atmospheric pressure varied up to a maximum value of 1044 mbar. The wound chamber and media were held at  $37^{\circ}\text{C}$  for 25 hours. In one set of wound chambers continuous flow was maintained. In 10 a second set of chambers 6 cycles of empty/ fill were performed with each fill or empty phase lasting 1 hour.

In controls where either

- 15 a) it was operated as an empty/fill system with 6 x cycles of 1 hour empty/ 1 hour fill over a total of 25 hours
  - b) the heat exchanger unit is omitted,
- the survival and growth of the fibroblasts is inhibited.

However, when the nutrient medium flow in the first circuit is

- 20 a) is delivered continually to the minucell chamber and the resultant nutrient medium is at the same time continually aspirated from the minucell chamber under vacuum was set at 950 mbar and where atmospheric pressure varied up to a maximum value of 1044 mbar.
- b) And passes through a heat exchanger so that the temperature of the 25 nutrient media bathing the cells reaches between  $35^{\circ}\text{C}$  and  $37^{\circ}\text{C}$ ,

the fibroblasts survive and proliferate to a greater extent during a 25 hour period than the control empty/fill circuits.

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| Conditions   | Mean of cell activity*<br>after 25 hours. N=3 |
|--|---|
| Baseline cell activity prior to<br>introduction to wound chamber | 0.25  |
| Continuous flow (SIA) flow at<br>room temperature                | 0.39  |
| Continuous flow (SIA) plus<br>heat (37°C)                        | 0.45  |
| Fill empty 6 cycles at room<br>temperature                       | 0.24  |
| Fill empty 6 cycles plus heat<br>(37°C)                          | 0.38  |

\*Cell activity measured with a WST (Tetrazolium based mitochondrial dehydrogenase activity assay).

5. The combination of heat (37°C) and continuous fluid flow at  $0.2 \text{ ml min}^{-1}$  with waste fluid removal under vacuum of no more than 10% atmospheric pressure, 950 mbar and atmospheric pressure varied up to a maximum value of 1044 mbar, enhances the cell response necessary for wound healing more than the fill empty fill pattern under vacuum.